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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE REVLIMID & THALOMID
PURCHASER ANTITRUST LITIGATION

Case No. 2:19-cv-07532

FRATERNAL ORDER OF POLICE, MIAMI
LODGE 20, INSURANCE TRUST FUND; *et al.*,

Case No. 2:22-cv-06694

Plaintiffs,

v.

CELGENE CORPORATION, BRISTOL-MYERS
SQUIBB COMPANY and TEVA
PHARMACEUTICALS USA, INC.,

**AMENDED CLASS ACTION
COMPLAINT**

Defendants.

DEMAND FOR JURY TRIAL

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Plaintiffs Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund and Jacksonville Police Officers and Fire Fighters Health Insurance Trust, Carpenters and Joiners Welfare Fund and Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund bring this class action, on behalf of themselves and all others similarly situated (the "Class," as defined below), against Celgene Corporation, Bristol-Myers Squibb Company ("BMS"), and Teva Pharmaceuticals USA, Inc., based on personal knowledge as to themselves and upon information and belief as to all other allegations, and allege as follows.

I. INTRODUCTION

1. Fair competition would have limited the price of a 30-day supply of cancer prescription drug Revlimid to less than \$800. Defendants instead are able to charge more than \$18,000 for the brand version and to sell the generic version for nearly the same price. This Amended Class Action Complaint explains how the Defendants' blatant violation of the antitrust law has allowed them to charge more than 22 times the competitive price for Revlimid and, unless the Court enjoins their ongoing unlawful conduct, to steal more than \$30 billion from Revlimid purchasers.

2. In 2005, Celgene successfully developed a thalidomide analog, Revlimid (lenalidomide), and obtained FDA approval to market it for a specific chromosomal variant of myelodysplastic syndromes. Celgene would go on to obtain FDA approvals for additional Revlimid indications, including for a subset of multiple myeloma patients in 2006, and later for a subset of mantle cell lymphoma patients in 2013.

3. In 2010, Natco Pharma Limited developed a generic version of Revlimid, and Celgene promptly sued Natco for patent infringement. The effects of generic competition for a brand drug are predictable: sales switch quickly from the brand drug to the generic, which is

priced at a fraction of the price of the brand drug. And as generic prices fall further as more generics enter the market, purchasers shift from the brand drug to a generic version. In short, a brand manufacturer's profits fall dramatically when a generic enters the market. To forestall those lost profits, some unscrupulous brand manufacturers pay the generic manufacturers to delay entering the market—they pay for delay.

4. That is exactly what happened here. After Celgene sued Natco for patent infringement, the parties entered into a December 2015 settlement agreement that contained a “reverse payment” to Natco—*i.e.*, a payment from the patent holder and patent-litigation *plaintiff*, Celgene, to the patent-litigation *defendant* in the patent lawsuit, Natco. In exchange, Natco agreed to stay out of the market until March 2022. The payment took the form of a volume-limited, royalty-free license, beginning in March 2022, that contained restraints ensuring that neither Celgene nor any other generic manufacturer would compete with Natco in the generic sector of the marketplace from March 2022 through September 2022. The restraints further ensured that from October 2022 through January 2026 Natco would continue to sell in the generic sector with no competition from Celgene and only significantly restrained competition from any other generic manufacturer.

5. Celgene and Natco allocated the Revlimid market between them: Celgene got the entire market from 2015 to March 2022, and now Natco gets a volume-limited but high-profit portion of the generic sector of the market from March 2022 through January 2026. That market-allocation agreement is blatantly unlawful under antitrust law.

6. To prevent other generic manufacturers from upending the anticompetitive scheme by avoiding Celgene's weak patents and marketing a generic version of Revlimid before Natco's agreed entry date in March 2022, Celgene and Natco included in their agreement several

deterrent provisions aimed at other competitors, including: (a) if another generic manufacturer succeeded in entering the market before March 2022, Natco could enter on that earlier date; (b) Celgene would not grant a license to any other manufacturer to enter the market sooner than 180 days after Natco launched its generic in March 2022; and (c) Celgene would not grant a license to any other manufacturer to sell a volume of generic product greater than Natco's allocated amount. These restraints deterred other generic manufacturers from continuing to challenge Celgene's patents. They also put a price floor under the generic sector—the volume limitations ensured that neither Natco nor the other generic manufacturers could garner more sales by cutting their prices to Plaintiffs and other purchasers.

7. Those deterrents ensured that, no matter the amount of resources another manufacturer might expend to overcome Celgene's patents, it could not enter the market sooner than Natco or enter without the volume limitations that restrain Natco. Under the unlawful Celgene/Natco agreement, another generic manufacturer's winning a patent lawsuit against Celgene would trigger Natco's immediate entry. Nor could the other manufacturer use the leverage of a patent challenge to negotiate a better volume deal or a better entry date from Celgene; the Celgene/Natco pact prohibited Celgene from providing a license for market entry until 180 days after Natco's entry, or for a sales volume greater than Natco's.

8. In the years following the December 2015 unlawful payment from Celgene to Natco, Celgene settled patent litigation with each of the other generic manufacturers discussed below, including Alvogen, Dr. Reddy's, Cipla, Apotex, Zydus, and Mylan, by entering into agreements with similar reverse payments. In each case, the generic manufacturer agreed to stop challenging Celgene's patents in exchange for a volume-limited, royalty-free license to sell generic Revlimid into the price-protected market during the period from September 2022 to

January 2026. And each of the agreements also included deterrents like those in the Celgene and Natco deal. Like that deal, each of these market-allocation agreements is also blatantly unlawful under antitrust law.

9. The Defendants unlawfully closed every pathway to any generic competition before March 2022 and forestalled unrestrained generic competition until February 2026. The Defendants are maintaining and sharing a monopoly in the sale of Revlimid and its generic equivalents where monopoly should not—and would not—exist under lawful, competitive practices.

10. That unlawful monopoly is extremely valuable, and Celgene wasted no time in exploiting it. Following its unlawful payments to Natco and throughout the period that it was entering into similar agreements with the other generic manufacturers, Celgene continued its practice of consistent and egregious price hikes intended to increase its monopoly profits. Revenue from its U.S. sales of Revlimid skyrocketed from \$3.5 billion in 2016 to \$8.7 billion in 2021. Since 2014, Celgene has sold over \$40 billion worth of Revlimid in the U.S. It is now the second-highest grossing drug worldwide.

11. In 2019, Celgene announced that it was being acquired by Defendant BMS for \$74 billion. At the time, Revlimid accounted for over 60% of Celgene's revenue. "The companies' public statements and filings with the Securities and Exchange Commission make clear that Revlimid, which had nearly \$10 billion in annual revenue, was a key asset in the transaction." U.S. House Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigations: Celgene and Bristol-Myers Squibb—Revlimid* (Sept. 30, 2020 at pg. 17). BMS reported more than \$12.1 billion in Revlimid revenue in 2020, its first full year following the Celgene acquisition.

12. The Defendants' unlawful scheme also resulted in an outrageously high price for the generic product when Natco finally entered the market in March 2022. As a result of the repeated, exorbitant price increases taken during the extended monopoly period, by March 2022 Defendants were able to charge more than \$18,277 for a 30-day supply of the brand version and virtually the same price for the generic version.

13. On behalf of themselves and all other indirect purchasers of brand and generic Revlimid, Plaintiffs bring this lawsuit to recover damages for the overcharges they have already paid and to obtain equitable relief to put a stop to the ongoing harm caused by the Defendants' anticompetitive conduct.

II. PARTIES AND NON-PARTIES

14. Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund ("FOP") is a governmental plan established and funded through contribution from the City of Miami and the plan's members, who are current and retired sworn officer from the City of Miami Police Department and their dependents. FOP was established pursuant to a Trust Agreement for the purpose of providing medical, surgical, and hospital care benefits, including prescription drug benefits, to its members. FOP maintains its principal place of business in Miami, Florida. FOP purchased and/or provided reimbursement for some or all of the purchase price of Revlimid or its AB-rated generic in Florida and Kansas at supracompetitive prices during the class period and, thus, suffered antitrust injury as a result of Defendants' unlawful conduct.

15. Plaintiff Jacksonville Police Officers and Fire Fighters Health Insurance Trust ("Jacksonville Trust"), is a health insurance trust that provides medical coverage, including pharmacy benefits, to its members. Jacksonville Trust is organized under the laws of the State of

Florida, with its principal place of business at 625 Stockton Street, Jacksonville, Florida 32204. Jacksonville Trust purchased and/or provided reimbursement for some or all of the purchase price of Revlimid or its AB-rated generic in Florida, Tennessee, and Kansas at supracompetitive prices during the class period and, thus, suffered antitrust injury as a result of Defendants' unlawful conduct.

16. Plaintiff Carpenters and Joiners Welfare Fund ("Carpenters") is a multi-employer "welfare plan" as defined under 29 U.S.C. §1002 that provides its eligible members and their dependents with health-care benefits through the Carpenters Plan, which is a self-insured health care plan. Carpenters maintains its principal place of business is at 3001 Metro Drive No. 500, Bloomington, Minnesota. Carpenters purchased and/or provided reimbursement for some or all of the purchase price of prescription drugs for its members in multiple states, including Minnesota, Wisconsin, Iowa, South Dakota, and North Dakota. Carpenters purchased and/or provided reimbursement for some or all of the purchase price Revlimid or its AB-rated generic at supra-competitive prices during the class period in at least Minnesota and Wisconsin and, thus, suffered antitrust injury as a result of Defendants' unlawful conduct.

17. Plaintiffs Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund (collectively "Local 237") are two related health and welfare benefit plans headquartered and with a principal place of business in New, York, New York. Local 237 administers the assets of defined contribution plans formed to provide certain benefits including prescription drug benefits. Local 237 provides health and welfare benefits to active and retired members and participants who reside in numerous locations in the United States. Local 237 purchased and/or provided reimbursement for purchased and/or provided reimbursement for some or all of the purchase price of Revlimid or its AB-rated generic in some or all of the purchase price

other than for re-sale, in New York, Florida, North Carolina, New Jersey, Pennsylvania, Tennessee, Michigan, Kansas, Georgia, and Alabama at supracompetitive prices during the class period and, thus, suffered antitrust injury as a result of Defendants' unlawful conduct.

18. Defendant Celgene Corporation ("Celgene") is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901. Celgene manufactures and markets Revlimid in the United States. Celgene was a party to the unlawful agreements alleged herein. In November 2019, Celgene was acquired by defendant Bristol-Myers Squibb Company and became a wholly owned subsidiary of BMS.

19. Defendant Bristol-Myers Squibb Company ("BMS") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 430 E. 29th Street, 14 FL, New York, New York 10016. BMS joined and adhered to the unlawful agreements alleged herein.

20. Except where otherwise noted, Defendants Celgene and BMS are collectively referred to herein as "Celgene."

21. Non-Party Natco Pharma Limited ("Natco") is an Indian drug manufacturer headquartered at Natco House, Road No. 2, Banjara Hills, Hyderabad-500, 034, India. Natco develops and markets drugs throughout the world, including in the United States. In September 2010, Natco filed the first Abbreviated New Drug Application ("ANDA") for generic Revlimid in 5mg, 10mg, 15mg and 25mg strengths. In December 2010, Natco announced a marketing and development agreement for generic Revlimid with a marketing partner, Watson Pharmaceuticals, Inc. ("Watson"), and Watson's subsidiary, Arrow International Limited ("Arrow").

22. Defendant Teva Pharmaceuticals USA, Inc. (“Teva”) is a Delaware corporation having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Teva acquired Watson and Arrow, Natco’s marketing partners for generic Revlimid. Teva launched Natco’s generic Revlimid product in March 2022, pursuant to the terms of the unlawful reverse-payment and market-allocation agreement described in detail below.

23. Non-Party Natco and Defendant Teva are sometimes collectively referred to herein as “Natco.”

24. Non-Party Lotus Pharmaceutical Co., Ltd. (“Lotus”) is a Taiwanese drug manufacturer headquartered at 17F, No. 227, Song Ren Rd., Xin Yi District, Taipei City 110, Taiwan. Alvogen Group, Inc., the parent corporation of Defendant Alvogen Pine Brook, LLC, is Lotus’s majority shareholder.

25. Non-Party Alvogen Pine Brook, LLC (“Alvogen”) is a Limited Liability Company organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Bloomfield Avenue, Pine Brook, New Jersey 07058.

26. Except where otherwise noted, Non-Parties Lotus and Alvogen are collectively referred to herein as “Alvogen.” Alvogen launched its generic Revlimid product in September 2022, pursuant to the unlawful reverse-payment and market-allocation agreement with Celgene described below.

27. Non-Party Dr. Reddy’s Laboratories Ltd. is an Indian drug manufacturer headquartered at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. Together with its U.S. subsidiary described below, it launched a generic Revlimid product in September 2022, pursuant to the unlawful reverse-payment and market-allocation agreement with Celgene described below.

28. Dr. Reddy's Laboratories, Inc. is a U.S. subsidiary of Dr. Reddy's Laboratories Ltd., organized under the laws of New Jersey, with a principal place of business at 107 College Road East, Princeton N.H. 08540. Together with its parent corporation, it is sometimes collectively referred to herein as "Dr. Reddy's." Dr. Reddy's launched a generic Revlimid product in September 2022, pursuant to the unlawful reverse-payment and market-allocations agreement with Celgene described below.

29. Non-Party Cipla Ltd. ("Cipla") is an Indian drug manufacturer headquartered at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400013 India. Cipla launched a generic Revlimid product in or about September 2022, pursuant to the unlawful reverse-payment and market-allocations agreement with Celgene described below.

30. Non-Party Apotex Inc. ("Apotex") is a Canadian drug manufacturer headquartered at 150 Signet Drive, Toronto, Ontario M9L 1T0, Canada. Apotex launched a generic Revlimid product in September 2022 pursuant to the unlawful reverse-payment and unlawful market-allocations agreement with Celgene described below.

31. Non-Party Zydus Pharmaceuticals (USA), Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Zydus Pharmaceuticals (USA) Inc. is a wholly owned subsidiary of Zydus Lifesciences Ltd.

32. Non-Party Zydus Lifesciences Ltd., f/k/a Cadila Healthcare Ltd., is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad 308815, Gujarat, India.

33. Except where otherwise noted, Zydus Pharmaceuticals (USA), Inc. and Zydus Lifesciences Ltd. are collectively referred to herein as "Zydus." Zydus launched a generic

Revlimid product in September 2022 pursuant to the unlawful reverse-payment and market-allocations agreement with Celgene described below.

34. Non-Party Mylan Pharmaceuticals Inc. (“Mylan”) is a corporation organized and existing under the law of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan launched a generic Revlimid product in or about September 2022 pursuant to the unlawful reverse-payment and market-allocations agreement with Celgene described below.

35. All of the Defendants’ wrongful actions described in this Amended Class Action Complaint are part of, and in furtherance of, the unlawful restraints of trade alleged herein, and were authorized, ordered, and/or undertaken by the Defendants’ various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants’ affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants.

III. JURISDICTION AND VENUE

36. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants. The Court further has jurisdiction over this action pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants’ violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2. The Court also has supplemental jurisdiction over the pendent state-law claims pursuant to 28 U.S.C. § 1367.

37. Defendants transact business within this district. Venue is appropriate within this district under 28 U.S.C. §1391(b) and (c), and Section 12 of the Clayton Act (15 U.S.C. § 22).

38. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to, persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. Regulatory Structure for Approval and Substitution of Generic Drugs

39. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), a manufacturer that creates a new drug must file a New Drug Application (“NDA”) in order to obtain approval from the Food and Drug Administration (“FDA”) to sell it. 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §§ 355(a) & (b).

40. With the filing of the NDA (and through amendments as necessary during the approval process), the manufacturer must inform the FDA of any patents that the manufacturer alleges “could reasonably be asserted” against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the listed patents expire. The FDA will then list these patents in its Approved Drug Products with Therapeutic Equivalence Evaluations publication, known as the “Orange Book.” Information about any later issued patent that the manufacturer alleges “could reasonably be asserted” against a generic manufacturer must be provided to the

FDA within 30 days of issuance of the patent; the FDA then publishes the patent in the Orange Book. 21 U.S.C. §§ 355(b)(1) & (c)(2).

41. The FDA relies completely on the brand manufacturer's truthfulness about a patent's validity and applicability. The FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

1. Hatch-Waxman Amendments

42. The Hatch-Waxman Amendments to the FDCA, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, i.e., absorbed at the same rate and to the same extent as the brand. 21 U.S.C. § 355(j)(8)(B). The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating, meaning the generics are therapeutically equivalent to and may be substituted for the brand (as well as other AB-rated generics of the brand).

43. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

44. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historic high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled \$21.6 billion; by 2013, total prescription drug revenues had climbed to more than \$329.2 billion, with generics accounting for 86% of prescriptions. *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the U.S. in 2013*, at 30, 51 (Apr. 2014). Generics are now dispensed 95% of the time when a generic version of the drug is available. *Id.* at 51.

2. ANDA Paragraph IV Certifications

45. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications for each patent the brand manufacturer has listed in the Orange Book as claiming the brand product. The generic manufacturer must certify that:

- a. no patent has been filed with the FDA (a “paragraph I certification”);
- b. the patent has expired (a “paragraph II certification”);
- c. the patent will expire on a particular date and the manufacturer does not seek to market its generic before that date (a “paragraph III certification”);
or
- d. the patent is invalid or will not be infringed by the generic manufacturer's proposed product (a “paragraph IV certification”).

21 U.S.C. § 355(j)(2)(A)(vii).

46. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic

filer within forty-five days of receiving notification of the paragraph IV certification, the FDA cannot grant final approval to the ANDA until the earlier of (i) the passage of 30 months, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA (referred to as a "30-month stay"). 21 U.S.C. § 355(j)(5)(B)(iii). Before that time, the FDA may grant "tentative approval," meaning all other scientific and regulatory requirements have been met and the application is approvable save for the 30-month stay/pending litigation. The FDA cannot, however, authorize the generic manufacturer to market its product (i.e., grant final approval) until one of the two conditions is met.

47. The high profit margins on brand drugs and the predictable effects of generic entry—sales switch quickly from the brand to the generic—create powerful financial incentives for brand manufacturers to sue any generic competitor that files an ANDA with a paragraph IV certification, even if the competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable. By simply listing the patents in the Orange Book and filing the lawsuit, the brand manufacturer can delay final FDA approval of an ANDA for up to 30 months.

3. ANDA Exclusivity Period

48. Generics may be classified as (i) first-filer generics, (ii) second-filer generics, or (iii) authorized generics.

49. As an incentive for manufacturers to seek approval of generic alternatives to brand drugs, the Hatch-Waxman Amendments provide that the first manufacturer to file an ANDA containing a paragraph IV certification (the "first filer") gets a period of protection from competition from other generic versions of the drug approved through the ANDA process ("ANDA Exclusivity"). That is, subject to certain limitations, the FDA is precluded from

approving any other generic version of the product through the ANDA process until 180 days after the first filer enters the market (the “180-day ANDA Exclusivity Period”). 21 U.S.C. § 355(j)(5)(B)(iv) & (D).

50. By creating a statutory mechanism to enable early infringement litigation following paragraph IV certifications, the Hatch-Waxman Amendments encourage generic manufacturers to test the validity of pharmaceutical patents and to invent around them. The idea is that bona fide litigation will result in rulings that either confirm legitimate patent protection or ferret out invalid, unenforceable, or narrow drug patents.

51. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. For example, an empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009—when the relevant patent case here was filed—found that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time. John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014) (“[P]atentees won only 164 of the 636 definitive merits rulings, or 26%,” and “that number is essentially unchanged” from a decade ago.).

52. An applicant that is otherwise eligible for the 180-day ANDA Exclusivity Period can forfeit it. As relevant here, a first filer forfeits its 180-day ANDA Exclusivity Period if the first filer fails to obtain tentative approval of its ANDA within 30 months after the application is filed. 21 U.S.C. 355 § (j)(5)(D)(i)(IV).

53. The Hatch-Waxman Amendments thereby created a statutory mechanism to enable generic manufacturers that were not the first to file a paragraph IV certification (a

“second filer”) to enter the market before the first filer, despite its 180-day ANDA Exclusivity Period. The Hatch-Waxman Amendments thus created incentives for second filers to try to enter the market before a first filer that, for example, settled its patent litigation by accepting a reverse payment in exchange for a delayed entry date (see Section V(D) below).

B. Competitive Effects of AB-rated Generic Competition

54. AB-rated generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand version is their price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a brand product and its generic version, or between generic versions of the same drug, is price. Typically, generics are at least 10% to 20% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 48% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the marketing of a generic usually results in significant cost savings for all drug purchasers.

55. Since passage of the Hatch-Waxman Amendments, every State has adopted “generic substitution” laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing doctor has specifically ordered otherwise). As a result of generic substitution laws and other institutional features of the pharmaceutical marketplace, the marketing of AB-rated generics results both in rapid price decline and rapid shift of unit sales from the brand to the generic product. Once a generic equivalent enters the marketplace, the generic quickly captures sales of the branded drug, often garnering 80% or more of unit sales within the first six months. The FTC found that, on average,

within a year of generic entry, generics had captured 90% of brand unit sales and (with multiple generics on the market) prices had dropped 85%. *See FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010) (“FTC Staff Study”), <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

56. According to the FDA and the FTC, the greatest price reduction occurs when the number of generics in the market goes from one to two. While the availability of just one generic may result in a near-term retail price of the generic of 10% to 20% less than the brand, the entry of a second generic competitor typically results in near-term retail price reduction of about 48% off the brand price.

57. Brand manufacturers are well aware of the rapid erosion of brand sales caused by generic entry into the market. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to unlawful means.

C. Price Competition from Authorized Generics

58. The brand manufacturer has the right to sell a generic version of its own brand product—a so-called “authorized generic.” An authorized generic is essentially the brand product, manufactured and marketed under the authority of the brand manufacturer’s FDA-approved NDA, but sold in different—generic—packaging. A brand manufacturer does not need to file an ANDA, or obtain any additional FDA approvals, to market a chemically identical generic version of a drug for which it has received approval through the NDA process.

59. A product marketed as an authorized generic—whether marketed by the brand manufacturer itself or by its licensee—is not subject to the first filer’s 180-day ANDA Exclusivity Period. The first filer’s 180-day ANDA Exclusivity Period is effective only against other products marketed pursuant to an approved ANDA, not products marketed pursuant to an

approved NDA. Thus, a brand manufacturer (or its licensee) may market and sell an authorized generic during the first filer's 180-day ANDA Exclusivity Period.

60. Brand manufacturers price their authorized generics like other generics and compete on price with other generics. Entry of an authorized generic during the first filer's 180-day ANDA Exclusivity Period can mean generic prices drop immediately to half the price of the brand or less, resulting in substantial savings for purchasers. But even at such lower prices, the brand manufacturer profits by taking a portion of the generic market.

61. In fact, many brand manufacturers start selling (either on their own or through a licensee) an authorized generic a few months before the first filer generic enters the market in connection with its 180-day ANDA Exclusivity Period. Brand manufacturers do so in order to secure multi-year purchase contracts with direct purchasers and to "load the generic pipeline" at the expense of the first-filer generic.

62. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'" Kevin A. Hassett & Robert J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* at 3, Sonecon (May 2007). Another study gives three examples of authorized generics, finding that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand." Ernst R. Berndt, et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affairs 790, 796 (2007).

63. The FTC estimates that a brand manufacturer whose product faces generic competition increases its overall revenues by as much as 21% when it introduces an authorized

generic. FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact 62 (Aug. 2011), <https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>.

64. The generic manufacturers' trade association reported to Congress that in a three-year period (before some unscrupulous manufacturers started unlawfully agreeing not to compete with authorized generics) "the brands have launched an authorized generic during every 180-day generic exclusivity period." GPhA Letter to Senate Special Committee on Aging at 5 (Jul. 27, 2006).

65. As a result, a competitive pharmaceutical marketplace includes authorized generic entry during the 180-day ANDA Exclusivity Period. While the first filer enjoys the exclusive right to sell the only ANDA-approved generic product during that six-month period, the prices at which it can do so are limited by price competition from authorized generics. Drug purchasers are intended to—and do, indeed—benefit from lower prices resulting from authorized generic entry during and after the 180-day ANDA Exclusivity Period.

D. Manufacturers' Motive to Conspire

66. In the absence of generic competition, brand manufacturers can usually sell the brand drug for a price far above the marginal cost of production, which allows them to generate profit margins in excess of 70% (and sometimes up to 98%) on hundreds of millions of dollars in sales. Economists refer to this ability to generate such high profit margins as "market power." When generics enter the market, however, they quickly take 90% or more of the total unit sales of the drug. And when multiple generics are in the market, competition between them drives down the price of the drug to near the marginal cost of production. This price competition delivers enormous savings to drug purchasers.

67. The brand and generic manufacturers have a collective interest in preventing or forestalling this competition. If they work together to prevent or delay competition, they can maintain the excessively high profit margins previously enjoyed only by the brand manufacturer and split the resulting excess profits amongst themselves. They can keep for themselves the enormous savings that price competition would have delivered to drug purchasers. The following series of charts demonstrates the manufacturers' common interest in delaying such competition.

68. A brand manufacturer in a marketplace without competition from generics receives all of the profits on all of the unit sales:



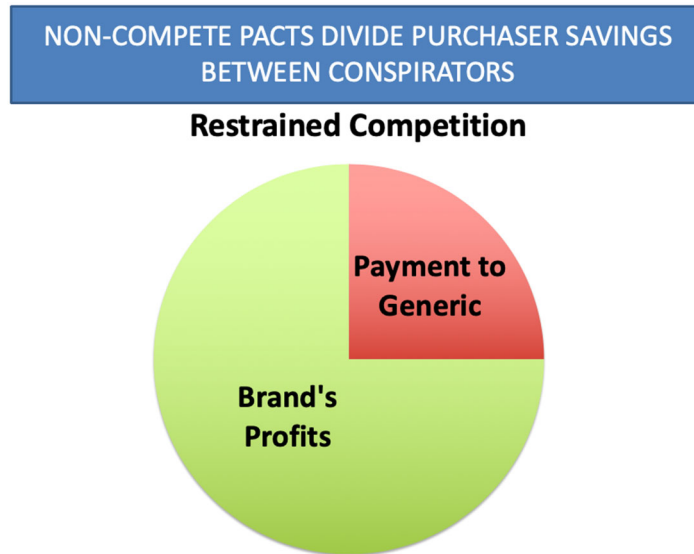
69. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturers sell most of the units, but at drastically reduced prices; and price competition delivers enormous savings to drug purchasers.

70. Competition converts what formerly were excess profits into purchaser savings:

COMPETITION DELIVERS SAVINGS TO PURCHASERS



71. To avoid this loss of profits, the brand and generic manufacturer can agree not to compete and, instead, to split the purchaser savings between themselves. For such an anticompetitive scheme to work, the brand and generic manufacturers need a way to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains. Payoffs from the brand manufacturer are a means by which the brand and generic manufacturers agree to divide between themselves the ill-gotten gains that the delayed competition makes possible. These unlawful pay-off deals are often referred to as “pay-for-delay,” “reverse-payment,” or “exclusion-payment” agreements. They are depicted here:



E. No-AG Payments

72. When brand manufacturers made unlawful payoffs to generic competitors in the 1990s, the payoffs took the form of cash payments. As a result of regulatory scrutiny, congressional investigations, and class-action lawsuits, however, brand and generic manufacturers have had to get more creative in hiding these unlawful payoffs in increasingly elaborate agreements.

73. One form of non-cash payoff is the no-authorized generic clause (a “No-AG Payment”). Pursuant to a No-AG Payment, the brand manufacturer agrees not to market an authorized generic version of the drug until after a period of time—often 180 days, but sometimes even longer—following the first filer’s entry into the market. In exchange, the generic manufacturer agrees to delay its entry into the market (i.e., its competition with the branded drug).

74. As noted above, the first filer’s 180-day ANDA Exclusivity Period does not prohibit the brand manufacturer from marketing its NDA-based authorized generic during the

180 days. The Hatch-Waxman Amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based authorized generic.

75. As also noted above, it is almost always financially advantageous for the brand manufacturer to begin marketing an authorized generic as soon as (or weeks or months before) the first generic manufacturer enters the market. Competition from an authorized generic, in turn, has a drastically negative effect on the first filer's revenue, typically cutting it by more than half. The competing authorized generic takes a substantial volume of the unit sales and drives prices lower—all to the benefit of drug purchasers.

76. In exchange for an agreement from the brand manufacturer not to market an authorized generic that would cause this substantial loss of revenue and profit, a generic first filer may be willing to agree to delay its entry into the marketplace. The additional profits that the brand manufacturer gains from the delayed onset of generic competition more than make up for the profits that it forgoes by not competing with an authorized generic.

77. The brand manufacturer gains from the delayed onset of generic competition. The first filer gains from the absence of generic competition after it finally does enter the market. And drug purchasers lose three times over: first by the delay in the onset of the first filer's entry into the market; second, by the absence of authorized-generic competition once the first filer finally enters; and third, by the "bottleneck" that the first filer's delayed entry causes—absent forfeiture of the first filer's 180-day ANDA Exclusivity Period, second filers cannot enter the market until the expiration of the first filer's artificially delayed 180-day ANDA Exclusivity Period.

1. No-AG Payment's Value to the Generic Manufacturer

78. A No-AG Payment is very valuable to the first filer. The first filer often earns the overwhelming portion of all of the profits it will ever make on the drug—as much as 80% of all that it will ever make—during its 180-day ANDA Exclusivity Period. It is almost always more lucrative for the first filer to delay entry and have 180 days on the market as the only generic than to enter the market earlier and have to compete against an authorized generic. That is why the first filer may be willing to agree to delay its entry in exchange for a No-AG Payment.

79. The Supreme Court has recognized that 180 days of generic exclusivity “can prove valuable, possibly ‘worth several hundred million dollars’” to the first filer. *FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). And because an authorized generic can reduce the value of that exclusivity by 50% on average, a “no-AG agreement . . . may be of great value to . . . the first-filing generic.” *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015).

80. Thus, “no-AG agreements are likely to present the same types of problems as reverse payments of cash.” *King Drug*, 791 F.3d at 404. As explained by the then-Chairman of the FTC:

Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, “if you go away for several years, I’ll give you \$200 million.” Now, the brand might say to the generic, “if I launch an AG, you will be penalized \$200 million, so why don’t you go away for a few years and I won’t launch an AG.”

Statement of Chairman Jon Leibowitz on the Release of the Commission’s Interim Report on Authorized Generics (June 2009), <http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf>.

81. Payoffs by means of No-AG Payments usually exceed the value that the first filer could have obtained even if it had won the patent infringement litigation. As a reward for winning the patent litigation, the Hatch-Waxman Amendments provide the first filer a period of 180 days of exclusivity as against other ANDA-based generic products. But the statute does not prevent the brand manufacturer from marketing an authorized generic during that time. By settling the patent case in exchange for a No-AG Payment, the first filer converts that six months of ANDA-based generic exclusivity into a period of total generic exclusivity, thus doubling its unit sales while making them at a vastly higher price.

2. No-AG Payment's Value to the Brand Manufacturer

82. While No-AG Payments are very valuable to the generic manufacturer, they would be very costly to the brand manufacturer if they did not have the intended anticompetitive effect of delaying generic entry. The brand manufacturer forgoes making half or more of the generic sales during the 180-day ANDA Exclusivity Period. Those forgone sales are a pure loss to the brand manufacturer because the addition of a second generic to the market does not significantly increase the rate at which purchasers substitute a generic for the branded product.

83. Of course, No-AG Payments are exceedingly valuable to the brand manufacturer—despite the loss of sales of an authorized generic—because they do in fact have the intended effect of causing the generic manufacturer to delay entering the market.

F. Deterrents to Second Filers

84. A brand manufacturer can also pay off the generic manufacturer by including in the agreement deterrent provisions designed to prevent other generic manufacturers (i.e., second filers) from entering the market before the delayed entry date to which the first filer has agreed.

Two types of these deterrents are Most-Favored-Entry clauses (“MFE”) and Most-Favored-Entry-Plus clauses (“MFEP”).

1. Most-Favored-Entry Clauses

85. A typical MFE provides that the first filer will delay entering the market until some specified date in the future; but if any other generic manufacturer (i.e., a second filer) succeeds in entering the market before that date, the first filer’s agreed entry date will be accelerated to the second filer’s earlier date.

86. The purpose and effect of an MFE is to delay generic entry by second filers. It dramatically reduces the incentives for potential generic competitors (i.e., potential second filers), who seek FDA approval after the first filer, to try to enter the market before the first filer. Absent the MFE in the agreement between the brand manufacturer and the first filer, a second filer could enter the market before the first filer under certain circumstances, thereby enjoying a substantial period where it would have the only ANDA-based generic product on the market.

87. When a second filer secures a final court judgment that the brand manufacturer’s patents are invalid or not infringed, the first filer forfeits its 180-day ANDA Exclusivity Period if it does not enter the market within 75 days of the court decision. 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb). The first filer would forfeit its statutory exclusivity period if, for example, it agreed with the brand manufacturer to delay entry until Year 4 and a second filer establishes patent invalidity in Year 2. Having agreed not to begin marketing until Year 4, the first filer could not enter the market within 75 days of the second filer’s favorable court decision in Year 2. The first filer would forfeit its 180-day ANDA Exclusivity Period.

88. An MFE allows the brand manufacturer and the first filer, through their joint conduct, to circumvent the statutory incentive for second filers to try to improve on the entry

date to which the brand manufacturer and first filer agreed. In the example above, absent an MFE, the Hatch-Waxman Amendments would allow the second filer to enter the market in Year 2 and enjoy a substantial period as the only ANDA-based generic product on the market. The first filer would be stuck on the sidelines until its agreed entry date. The prospect of being the only ANDA-based generic product on the market motivates a second filer to incur the substantial costs and burdens of trying to enter the market before the first filer's agreed entry date. An MFE eliminates that possibility and deters second filers from even trying.

89. MFEs result in delayed generic entry in at least two ways: (i) they deter second filers from trying to enter the market before the first filer's agreed entry date, and (ii) by eliminating the threat to the first filer's 180-day ANDA Exclusivity Period, they compensate the first filer for agreeing to delay its entry into the market. In short, MFEs eliminate second filers' competitive threat to the first filer, in return for which the first filer agrees to delay its entry into the market.

90. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—testified to Congress that MFEs “eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry” and have broad, negative implications for consumer access to generics:

[N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under this system. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.

Statement of Bernard Sherman, CEO, Apotex, Inc.,
<http://www.gpo.gov/fdsys/pkg/CHRG-111hhr67822/pdf/CHRG-111hhr67822.pdf> at 218 (March 31, 2009).

2. Most-Favored-Entry-Plus Clauses

91. An unscrupulous brand manufacturer could also use another type of second-filer deterrent to compensate the first filer for agreeing to delay entry into the market. A Most-Favored-Entry-Plus clause (“MFEP”) provides that the brand manufacturer will not grant a license to any other generic manufacturer to enter the market (under authority of the generic competitor’s ANDA) until a defined period of time after the first filer enters. The MFEP might provide, for example, that the brand manufacturer will not grant a license to any second filer to enter the market until 180 days after the first filer enters the market. The MFEP might include an agreement not to grant a license to a second filer to enter before the first filer under authority of the brand’s NDA.

92. The purpose and effect of an MFEP, like an MFE, is to pay off the first filer to get its agreement to delay its entry into the market. MFEPs also deter second filers from trying to enter the market before the first filer. Absent the MFEP, second filers could use their own challenges to the brand manufacturer’s patents as leverage to negotiate from the brand manufacturer a license to enter the market before the first filer, thereby enjoying a substantial period where it would have the only generic product on the market.

93. In short, the Hatch-Waxman Amendments leave open at least two pathways for second filers to enter the market before a first filer that has agreed to delay entry into the market. The second filer can win the patent litigation and trigger forfeiture of the first filer’s 180-day ANDA Exclusivity Period if it fails to enter the market within 75 days of the favorable court decision. The second filer can also negotiate an earlier entry date from the brand manufacturer. MFEPs and MFEs work together to deter second filers from trying to enter the market before the first filer’s agreed entry date and to compensate the first filer for agreeing to delay its entry into the market.

94. Through No-AG Payments, MFEs, and MFEPs, the brand manufacturer and the first filer can work together to close all of the pathways that Congress left open for earlier generic entry into the market.

V. DEFENDANTS' ANTICOMPETITIVE CONDUCT

95. Celgene filed, prosecuted, and listed 30 patents in the FDA Orange Book as claiming Revlimid. But those patents were weak and could not hold off competition from generic versions of the drug. Celgene acknowledged “that Revlimid revenue was so critical that any expiration of its patent protection sooner than anticipated ‘would be harmful to the combined company and could have a material adverse effect on its business, financial condition or results of operations.’” U.S. House Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigations: Celgene and Bristol-Myers Squibb—Revlimid* at 2 (Sept. 30, 2020). Facing imminent and certain generic erosion, Celgene engaged in a scheme to block generic competition by effectively paying generic drug manufacturer Natco to delay its market entry until March 2022 and, in doing so, blocked other generic entrants until September 2022. This anticompetitive conduct violated federal antitrust laws and harmed purchasers.

A. Approval of Brand Revlimid and its Related Patent

96. On April 7, 2005, Celgene submitted NDA No. 21-880 to the FDA, seeking approval to manufacture, market, and sell lenalidomide capsules under the brand name Revlimid, in strengths of 5 and 10 milligrams, for the treatment of patients with transfusion-dependent anemia because of specified myelodysplastic syndromes.¹

¹ Celgene’s application sought approval of Revlimid for low or intermediate-risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities.

97. On December 27, 2005, the FDA approved the manufacture, marketing, and sale of 5 and 10 milligram capsules of lenalidomide for the applied-for indication. The FDA granted a 5-year new-drug exclusivity, expiring on December 27, 2010.

98. The FDA later approved further strengths and indications for Revlimid, including: on June 29, 2006, approving 15 and 25 milligram capsules; on December 21, 2011, approving 2.5 milligram capsules; and on June 5, 2013, approving 20 milligram capsules.

99. Over the years, the FDA also awarded Celgene orphan-drug exclusivity for certain use indications with expiration dates including June 5, 2020; February 17, 2022; February 22, 2024; and May 28, 2026. Orphan-drug exclusivity is for a specific use and does not prevent generic competition for other approved uses of the drug.

100. Over time, Celgene obtained and listed in the FDA's Orange Book thirty patents claiming aspects of Revlimid and its uses.

101. The earliest of those listed patents is U.S. Patent No. 5,635,517 (the '517 patent), which includes a claim for the lenalidomide compound that is the active ingredient in Revlimid and also includes method claims encompassing the use of the lenalidomide compound to reduce undesirable levels of TNF α in a mammal. The term of the '517 patent was extended by 1,167 days based on the FDA review process. It expired on October 4, 2019.

102. The remaining 29 listed patents have expiration dates ranging from July 24, 2016, to March 28, 2028. They fall into three general categories: (i) patents claiming methods of treating disease with Revlimid; (ii) patents claiming methods of distributing drugs, like Revlimid, with dangerous side effects; and (iii) patents claiming drug-product compositions, including various chemical forms of lenalidomide.

103. **Patents Claiming Methods of Treating Disease.** Fourteen listed patents claim methods of treating various diseases by administering Revlimid alone or in combination with another active ingredient:

Patent No.	Earliest Effective Non-Provisional Filing Date	Issue Date	Expiration Date
6,281,230 ('230 patent)	Aug 22, 1996	Aug 28, 2001	Jul 24, 2016
7,189,740 ('740 patent)	Apr 11, 2003	Mar 13, 2007	Apr 11, 2023
7,468,363 ('363 patent)	May 15, 2003	Dec 23, 2008	Oct 07, 2023
7,968,569 ('569 patent)	May 15, 2003	Jun 28, 2011	Oct 07, 2023
8,404,717 ('717 patent)	Apr 11, 2003	Mar 26, 2013	Apr 11, 2023
8,492,406 ('406 patent)	May 15, 2003	July 23, 2013	Oct 27, 2023
8,530,498 ('498 patent)	May 15, 2003	Sep 10, 2013	May 15, 2023
8,648,095 ('095 patent)	May 15, 2003	Feb 11, 2014	May 15, 2023
8,741,929 ('929 patent)	Aug 01, 2007	Jun 3, 2014	Mar 08, 2028
9,056,120 ('120 patent)	Apr 11, 2003	Jun 16, 2015	Apr 11, 2023
9,101,621 ('621 patent)	May 15, 2003	Aug 11, 2015	May 15, 2023
9,102,622 ('622 patent)	May 15, 2003	Aug 11, 2015	May 15, 2023
9,155,730 ('730 patent)	May 15, 2003	Oct 13, 2015	May 15, 2023
9,393,238 ('238 patent)	May 15, 2003	Jul 19, 2016	May 15, 2023

104. **Patents Claiming Methods of Distributing High-Risk Drugs.** Ten listed patents claim methods of distributing drugs like Revlimid, which poses a high risk of fetal side effects, to ensure that users are instructed about the dangers:

Patent No.	Earliest Effective Non-Provisional Filing Date	Issue Date	Expiration Date
6,045,501 ('501 patent)	Aug 28, 1998	Apr 04, 2000	Aug 28, 2018
6,315,720 ('720 patent)	Oct 23, 2000	Oct 23, 2020	Oct 23, 2020
6,561,976 ('726 patent)	Aug 28, 1998	May 13, 2003	Aug 28, 2018
6,561,977 ('977 patent)	Oct 23, 2000	May 13, 2003	Oct 23, 2020
6,755,784 ('784 patent)	Oct 23, 2000	Jun 29, 2004	Oct 23, 2020
6,908,432 ('432 patent)	Aug 28, 1998	Jun 21, 2005	Aug 28, 2018
8,204,763 ('763 patent)	Aug 28, 1998	Jun 19, 2012	Aug 28, 2018
8,315,886 ('886 patent)	Oct 23, 2000	Nov 20, 2012	Oct 23, 2020
8,589,188 ('188 patent)	Aug 28, 1998	Nov 19, 2013	Aug 28, 2018
8,626,531 ('531 patent)	Oct 23, 2000	Jan 07, 2014	Oct 23, 2020

105. **Patents Claiming Specific Drug-Product Compositions.** Five listed patents claim drug-product compositions, including specific chemical forms of lenalidomide:

Patent No.	Earliest Effective Non-Provisional Filing Date	Issue Date	Expiration Date
6,555,554 ('554 patent)	Aug 22, 1996	Apr 29, 2003	Jul 24, 2016
7,119,106 ('106 patent)	Aug 22, 1996	Oct 10, 2006	Jul 24, 2016
7,465,800 ('800 patent)	Sep 03, 2004	Dec 16, 2008	Apr 27, 2027
7,855,217 ('217 patent)	Sep 03, 2004	Nov 21, 2010	Nov 24, 2024
8,288,415 ('415 patent)	May 7, 1999	Oct 16, 2012	Jul 24, 2016

106. Each of the listed patents was vulnerable to challenges regarding validity, enforceability, and non-infringement. The patents' vulnerability meant that none stood as

legitimate impediments to generic competition, but by listing them in the Orange Book, Celgene ensured that every potential generic competitor would have to address them.

107. For example, separate and apart from unenforceability and other invalidity and non-infringement challenges, any meaningful claims of the ten listed patents directed to methods of distributing drugs could not survive an obviousness challenge by a competitor. The vulnerability of these patents was demonstrated when all claims of the '501 patent were challenged in a Patent Office *inter partes* review and found unpatentable as obvious, a finding that was affirmed by the United States Court of Appeals for the Federal Circuit. Similarly, 31 of the 32 method claims of the '720 patent were challenged in a Patent Office *inter partes* review and found unpatentable as obvious. That finding also was affirmed by the Federal Circuit.²

B. Natco files the First ANDA Threatening Celgene's Patents.

108. Natco was the first to file an ANDA seeking approval to manufacture, market, and sell a generic version of Revlimid, filing ANDA No. 201452 for generic approval for lenalidomide capsules at dosages of 5, 10, 15, and 25 milligrams.³ As the first to submit a substantially complete ANDA for lenalidomide, Natco was eligible for the 180-day ANDA Exclusivity Period for generic Revlimid capsules at dosages of 5, 10, 15, and 25 milligrams when it received final approval.

109. In connection with its ANDA No. 201452, Natco provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of at least the

² See IRR2015-1096, IPR2015-01102, IPR2015-01103, and IPR2015-01092, and *Celgene v. Peter*, 931 F.3d 1342 (Fed. Cir. July 30, 2019), affirming same (*cert. denied*, 141 S.Ct. 132 (June 22, 2020)).

³ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. 233, Amended Answer, Affirmative Defenses and Counterclaims to Plaintiff's Fifth Amended Complaint, (Answer ¶ 29, Counterclaims ¶ 23) (Natco's Fifth Amended Answer).

'517, '501, '720, '554, '976, '977, '784, '106, and '800 patents are invalid, unenforceable, or will not be infringed by the activities described in Natco's ANDA.

110. On or around August 30, 2010, Natco sent Celgene written notice of its ANDA certification and provided Celgene with its factual and legal basis supporting its position that the '517, '501, '720, '554, '976, '977, '784, '106, and '800 patents (among others) are invalid, unenforceable, or will not be infringed by Natco's ANDA products.⁴

111. On October 8, 2010, Celgene sued Natco in this Court for alleged infringement of the '517, '501, '720, '554, '976, '977, '784, '106, and '800 patents.⁵

112. Between the filing of Celgene's original complaint and May 6, 2013, Natco sent Celgene written notice of additional paragraph IV certifications,⁶ and Celgene amended its complaint five times to add patent claims and defendants, including Arrow (the exclusive distributor for Natco's ANDA products) and Watson Laboratories (the successor of Arrow International).⁷

113. In addition, on July 20, 2012, Celgene brought a second action against Natco in this Court, alleging infringement of the '517, '230, '740, and '569 patents, as well as infringement to two additional patents: U.S. Patent No. 7,977,357 ('357 patent) and U.S. Patent

⁴ Natco's Fifth Amended Answer, Answer ¶ 31.

⁵ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. 1, Complaint for Patent Infringement

⁶ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. 233, Amended Answer, Affirmative Defenses and Counterclaims to Plaintiff's Fifth Amended Complaint, (Answer ¶¶ 33, 35, Counterclaims ¶¶ 32, 35) (Natco's Fifth Amended Answer).

⁷ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. 1, 16, 52, 204, 210, 215.

No. 8,193,219 ('219 patent). *See* Civil Action No. 12-4571 (D.N.J. 2012). The two actions were consolidated by the Court.⁸

114. For each of the complaints filed by Celgene, Natco filed an answer, including affirmative defenses and counterclaims, (1) denying that its lenalidomide capsules that are the subject of ANDA No. 201452 would infringe claims of any of the asserted patents, (2) asserting that the asserted patents are invalid, and (3) asserting unenforceability (because of Celgene's inequitable conduct during prosecution) of the asserted patents directed to methods of distributing drugs like Revlimid (which poses a high risk of fetal side effects) to ensure that users are instructed to the dangers of using the drug.⁹ In addition to seeking a favorable declaration on each of the patents asserted by Celgene against it, Natco's counterclaims also sought a favorable declaration with respect to four of Celgene's other related but unasserted patents: U.S. Patent Nos. 6,767,326 (the '326 patent), 6,908,432 (the '432 patent), 7,855,217 (the '217 patent), and 8,204,763 (the '763 patent).¹⁰

C. Celgene's Patents Were Weak and Could Not Preclude Early Generic Entry.

115. The *Celgene v. Natco* litigation commenced on October 8, 2010, and terminated after the parties entered into a settlement agreement and tendered a Consent Judgment on January 4, 2016.¹¹ The Consent Judgment was entered before the rescheduled close of expert

⁸ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc.149; 2:12-cv-4571 (D.N.J.), Doc. 1, 25.

⁹ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. Nos. 9, 18 60, 208, 213, and 233, Amended Answer, Affirmative Defenses and Counterclaims to Plaintiff's Original, First, Second, Third, Fourth and Fifth Amended Complaint, respectively.

¹⁰ *Id.*

¹¹ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. No. 466, January 4, 2016, Consent Judgment.

discovery in March 2016¹² but after the Court had conducted a *Markman* hearing on disputed claim constructions and issued a Markman Opinion.¹³

116. On the whole, the Court’s Markman Opinion favored Natco. The Court construed certain claims of the ’230 and ’554 patents to be limited to specific stereochemical configurations of lenalidomide, which solidified noninfringing design-arounds. The Court did not accept Natco’s proposed claim construction for the “hemihydrate” claim term in claims 1-14 of the ’800 patent, but the Court’s adopted construction exposed the ’800 patent (as well as other patents in its family) to additional invalidity contentions. Indeed, after the Court issued its Markman Opinion, Natco moved for leave to supplement its invalidity contentions, and the Court granted Natco’s motion over the strong opposition of Celgene.¹⁴

117. The consolidated action involved 20 patents (either asserted by Celgene against Natco or introduced by Natco in its declaratory judgment counterclaims). Natco had strong defenses to all those patents. None presented a reason for Natco to agree to wait until 2022 to enter the market with a generic Revlimid, let alone enter the market in 2022 at a volume-limited amount until January 31, 2026.

118. Nine of the 20 patents claimed methods of distributing high-risk drugs—like Revlimid, which poses a high risk of fetal side-effects—to ensure that users are instructed to the dangers of using the drug. Those nine distribution patents are the ’501, ’720, ’976, ’977, ’784, ’886 ’326, ’432, and ’763 patents, and they are part of two patent families. The ’326, ’432, ’763,

¹² *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. No. 465, December 5, 2015, Order extending discovery deadlines.

¹³ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. No. 312, May 27, 2014, Markman Opinion.

¹⁴ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. No. 367, November 18, 2014, Order.

and '976 patents all relate back to the application that matured into the '501 patent; the '977, '784, and '886 patents all relate back to the application that matured into the '720 patent.

119. Natco not only asserted that Celgene's distribution patents were obvious and thus invalid but, in addition, that they are unenforceable because of Celgene's inequitable conduct—because during patent prosecution, Celgene had failed to provide to the USPTO prior-art that was material to the alleged patentability of the patents' claims. And, as discussed above, the weakness of the distribution patents is confirmed by what happened when those patents were challenged in a third-party *inter partes* review: the USPTO invalidated, as obvious in view of the prior art, all claims of the '501 patent and 31 of the claims of the '720 patent. The weakness of the distribution patents is further highlighted by Celgene's issuance of covenants not to sue Natco on the '326, '432, and '763 patents (which Natco had introduced in its counterclaims) in an effort to negate a case or controversy with respect to those patents.¹⁵

120. The remaining 11 of the 20 patents at issue likewise presented no reason for Natco to agree to stay out of the market.

121. Four of the patents (the '230, '554, '106, and '415 patents) had expiration dates of July 24, 2016, and on March 26, 2015, the parties advised the district court they had entered into a stipulation dismissing claims and defenses for those four patents in view of Natco's changing its paragraph IV certifications for those patents to Paragraph III certifications.¹⁶ By agreeing to forego FDA approval of its ANDA No. 201452 until those patents expired in July 2016, Natco

¹⁵ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Covenants Not to Sue, Doc. Nos. 24 and 145.

¹⁶ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. Nos. 401 and 402.

streamlined the case that would not reach a final adjudication until the four patents had expired. Those patents presented no basis for Natco to stay out of the market until 2022.

122. One of the patents (the '217 patent) claimed crystalline and hemihydrate forms of lenalidomide. Natco had put that patent in jeopardy through its declaratory judgment counterclaims. To shield the '217 patent from Natco's challenge, Celgene issued a covenant not to sue Natco on the '217 patent.¹⁷

123. Five of the patents (the '800, '717, '598, '357, and '219 patents) were directed to specific forms of lenalidomide or specific methods of use and dosing of lenalidomide. Setting aside Natco's invalidity defenses, the limited scope of those patents afforded ample noninfringing design-arounds. Indeed, the '800 patent is the only asserted patent having an expiration date later than January 31, 2026, and all 14 claims of the '800 patent are limited to a crystalline lenalidomide hemihydrate. As noted above, the district court's construction of "hemihydrate" increased the vulnerability of '800 patents to Natco's invalidity defenses and allowed for noninfringing forms—such as those provided in Celgene's own prior-art patents for lenalidomide, including the '517 patent that was issued several years before the application for the '800 patent was filed.

124. The last of the patents (the '517 patent) was the first patent listed in the Orange Book. Not only was that patent vulnerable to Natco's invalidity defenses. but, in the unlikely event that it survived Natco's invalidity challenge, the '517 patent expired on November 4, 2019—well before Natco's agreed, volume-limited entry in March 2022.

¹⁷ *Celgene Corp. v. Natco Pharma Limited et al.*, 2:10-cv-05197-SDW-LDW (D.N.J.), Doc. 140, Covenant Not to Sue.

D. Celgene Unlawfully Paid Natco to Delay Generic Entry.

125. On December 22, 2015, Celgene announced the settlement of litigation with Natco and its marketing partners, Watson and Arrow, relating to Celgene's Revlimid patents. Watson and Arrow were subsequently acquired by Teva. Natco's ANDA for generic Revlimid was finally approved by the FDA in March 2021. Teva launched Natco's generic Revlimid a year later, in March 2022, pursuant to the terms of the unlawful December 2015 settlement agreement between Celgene and Natco.

126. Celgene and Natco settled the patent lawsuit before the Court issued a ruling on the validity and/or infringement of Celgene's patents. To avert the substantial probability that Natco would prevail in court or launch a non-infringing generic Revlimid at risk, Celgene paid off its would-be competitor to delay generic entry, thus extending the period of Revlimid's supracompetitive profits. In exchange for the unlawful reverse payments it received, Natco agreed not to launch its generic version of Revlimid until March 2022, and only then in limited quantities over the next four years. This anticompetitive agreement will preclude unrestrained generic competition for Revlimid until February 1, 2026, forcing purchasers to continue paying supracompetitive prices for the drug long after generic entry.

127. When crafting the terms of their agreement, Celgene and Natco knew that other generic manufacturers would pose a competitive threat to each of them. Revlimid annual sales were already at the blockbuster level, and Natco was agreeing to delay unrestrained competition for 11 years. This created the incentive and ability for other generic manufacturers to enter the market in order to get a period of de facto market exclusivity. Congress, in the Hatch-Waxman Act, provided at least three pathways for second filers to enter the market ahead of a first filer that agreed to such a substantially delayed entry.

128. Congress provided in the FD&C Act's forfeiture provisions (see Section IV(A) above) that a second filer can jump ahead of the first filer by obtaining a judgment of invalidity or noninfringement as to the relevant patents. When a second filer obtains such a judgment, the first filer has 75 days to enter the market; if it fails to do so, it forfeits its 180-day ANDA Exclusivity Period. Having agreed to delay unrestrained entry to February 1, 2026, Natco would be stuck on the sidelines, unable to enter within 75 days of those judgments, and thus would have forfeited its 180-day ANDA Exclusivity Period.

129. Congress also provided in the FD&C Act that second filers that enter the market pursuant to Section viii statements are not subject to a first filer's 180-day ANDA Exclusivity Period. Each of those second filers had a substantial probability of entering the market long before February 1, 2026. Again, having agreed to delay unrestrained entry to February 2026, Natco would be stuck on the sidelines while other generic manufacturers entered before it.

130. Congress similarly provided in the FD&C Act that a first filer's 180-day ANDA Exclusivity Period prevents the FDA from approving only other ANDA-based products during that period. It does not prevent other generic manufacturers from entering the market pursuant to a license granted by the brand manufacturer under authority of its NDA. As noted in detail in Section V above, other generic manufacturers would have substantial probabilities of obtaining judgments that the Revlimid patents were invalid and not infringed. Those second filers could use the leverage of their patent challenges to negotiate a license from Celgene to enter the market under its NDA. This is yet another Congressionally authorized means by which Natco, having agreed to delay unrestrained entry until February 2026, would be stuck on the sidelines while other generic manufacturers entered the market, with Natco's 180-day ANDA Exclusivity Period powerless to stop them.

131. Celgene agreed to protect Natco from those threats; in exchange, Natco agreed to delay unrestrained entry until February 2026. Celgene paid Natco to delay.

132. Celgene's payment to Natco took at least five forms. First, Celgene paid Natco to delay its entry into the market by providing Natco a volume-limited, royalty-free license to sell generic Revlimid from March 2022 to January 2026.

133. Second, Celgene paid Natco to delay its entry into the market by providing Natco a Most-Favored-Quantity clause ("MFQ"). The MFQ provides in substance that Celgene will not provide a license (under the generic's ANDA or Celgene's NDA) to any second filer, for the period from March 2022 through January 31, 2026, to enter the market with a quantity of generic Revlimid greater than the quantity licensed to Natco. This payment shuts down another pathway—obtaining a license to enter the market—that Congress provided for second filers to enter an unrestrained market ahead of first filers. This restraint applies even after Natco's statutory 180-day ANDA Exclusivity Period expires.

134. Third, Celgene paid Natco to delay its entry into the market by providing Natco an MFE. The MFE provides in substance that, in the event a second filer enters the market before February 2026 without Celgene's permission (either by obtaining a judgment of invalidity or noninfringement or by relying on a Section viii statement), Natco's agreed entry date will be accelerated to the second filer's earlier date. This payment shuts down those two pathways that Congress provided for second filers to enter the market ahead of first filers.

135. Fourth, Celgene paid Natco to delay its entry into the market by providing Natco an MFEP. The MFEP provides in substance that Celgene would not provide a license to any second filer, including a license under Celgene's NDA, within 180 days of the date that Natco was permitted to enter with a restricted quantity of generic Revlimid (i.e., not before September

2022). This payment shuts down another pathway—obtaining a license to enter under the brand manufacturer’s NDA—that Congress provided for second filers to enter the market ahead of first filers that agreed to lengthy delays in entry.

136. Fifth, Celgene paid Natco to delay its entry into the market by providing Natco a No-AG Payment. The No-AG Payment provides in substance that Celgene will not, except in limited circumstances, enter the market with an NDA-based authorized-generic version of Revlimid during the period from March 2022 to January 31, 2026. With the MFE, MFEP, and MFQ in place, Celgene’s marketing of its own NDA-based authorized generic would only serve to take sales from Celgene’s own branded product.

137. Generally, when a first filer enters the market without any volume limitation, it lowers the price of its generic drug to the level sufficient to rapidly garner 80% or more of the total unit sales of the brand and generic drug. The addition of an authorized generic typically does not significantly accelerate the erosion of the brand units. The brand manufacturer is going to lose approximately 80% of the unit sales regardless of whether one or two generics enter the market. Therefore, the brand manufacturer markets its own authorized generic in order to take about half of the generic sales during the first filer’s 180-day ANDA Exclusivity Period, without increasing the erosion of its brand sales. Brand manufacturers of big-selling drugs encountering market entry by a generic with a 180-day ANDA Exclusivity Period almost always launch their own authorized generic. Absent the restraints agreed upon with Natco, Celgene would have almost certainly responded to Natco’s entry into the market with its own authorized generic.

138. Celgene and Natco’s agreement to significantly limit Natco’s unit sales upon its entry into the market fundamentally altered these economics. During its 180-day ANDA Exclusivity Period (as well as the balance of its first full year of entry), Natco could take only a

modest percentage of the unit sales (“a mid-single-digit percentage” of unit sales, according to Celgene’s press release regarding the settlement) rather than the 80% that a first filer would typically garner during that period. Had Celgene marketed its own NDA-based authorized generic during that period, it would have only eroded its own brand sales and would not have taken half of the generic sales, as would be expected in the usual scenario of a first filer entering the market with a 180-day ANDA Exclusivity Period and no volume limitation. Therefore, Celgene and Natco’s agreement to limit Natco’s unit sales during its 180-day ANDA Exclusivity Period was also a de facto agreement that Celgene would not enter the market with its own authorized generic during that period.

139. Collectively, these restraints created for Natco: (a) a period of generic exclusivity—March 2022 through August 2022—during which Celgene gave Natco a royalty-free license to sell a limited quantity of generic Revlimid as the only generic on the market; and (b) a period of price-protected generic competition—September 2022 through January 2026—with the MFE, MFEP, and MFQ deterring second filers from gaining unrestrained entry into the market and ensuring that Natco could continue making its volume-limited sales at a very high price despite the presence of other generics in the market.

140. Moreover, Celgene and Natco knew when entering into their agreement in December 2015 that this would be the restraints’ effect. When making the agreement, Natco knew that: (a) Celgene was willing to include the anticompetitive MFEs in settlement agreements with second filers; (b) given the accumulating effect of additional MFEs, it was in Celgene’s financial interest to include those clauses in agreements with all second filers; (c) the second filers would know that the Celgene/Natco agreement included volume limitations and an MFE, MFEP, and MFQ; (d) Celgene would likely grant volume-limited, royalty-free licenses—

essentially cash payments of tens of millions of dollars each—to the second filers; (d) given these disincentives and enticements, it was not in any second filer’s interest to incur the costs of patent litigation to try to enter the market before Natco; (f) the restraints’ deterrent effects would increase as Celgene included them in additional settlement agreements; and (g) second filers that settled after Natco would also know all of (a)-(f) above.

141. Natco concluded, correctly, that the restraints would protect it from competition from any other generic manufacturer until September 2022 and would allow it to sell in a price-protected market from September 2022 through January 2026.

142. In exchange for these payments from Celgene, Natco agreed to delay entry into the market until March 2022, and until February 2026 without any volume limitation.

143. The size of the payment from Celgene and BMS to Natco and Teva can be approximated. Under competitive conditions, there are typically three versions of a branded pharmaceutical available during the 180-day ANDA Exclusivity Period: the brand product itself, the first filer’s generic product, and the brand’s own NDA-based authorized generic. The two generic products quickly capture most of the market. The generics compete on price, bringing the price of the generic products down to no more than 40% of the brand price. After the exclusivity period expires, additional generics enter the market and drive the price of the generics down further, sometimes to as little as 5% of the brand price.

144. A No-AG Payment is an anticompetitive promise from the brand not to compete with the generic during its 180-day ANDA Exclusivity Period, made in exchange for a delay in generic entry. According to the FDA, a generic product in a market with only one generic seller

is priced at 61.4% of the brand price.¹⁸ While No-AG Payments injure purchasers by maintaining higher generic prices after generic entry, they have virtually no effect on generic penetration and thus allow purchasers to achieve modest savings on nearly all of their purchases of the relevant drug at the time of generic entry. And since No-AG Payments typically last only six months, they permit full-fledged (albeit belated) generic competition six months after initial generic entry.

145. No-AG Payments are more anticompetitive than cash payments because they create generic monopoly, rather than a generic duopoly, during the first six months after generic entry. In effect, No-AG Payments force purchasers to pay a portion of the compensation to the generic in the form of higher generic prices.

146. With a volume-limited license, the brand manufacturer can retain the entire share of the market not allocated to the generic and has no incentive to launch its own NDA-based authorized generic. The sales volume of the volume-limited generic is also fixed, so it has no incentive to reduce its price to increase its sales volume. A volume-limited generic entrant that faces no additional generic competition will price its product very close to the brand price, as Teva did here.

147. In 2015, when the Celgene-Natco settlement occurred, a reasonable estimate was that Celgene's monthly Revlimid sales would be approximately \$540 million in March of 2022. Under normal competitive conditions, Celgene would be expected to launch its own authorized generic, and the two generic products (Natco's and the authorized generic) would be expected to

¹⁸ R. Conrad and R. Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA: Generic Competition and Drug Prices (December 2019), available at <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drugprices> (last accessed March 29, 2022).

capture 70% or more of the total market from the brand. Assuming an equal split, Natco would capture 35% of the unit sales. Using a generic price equal to 61% of the brand price and a 70% gross profit margin, Natco would earn profits of approximately \$80 million during each month of its 180-day ANDA Exclusivity Period, or approximately \$484 million during the full 180-day ANDA Exclusivity Period. Upon expiration of the exclusivity period, additional competitors would enter, Natco's share of the market would decline, the generic discount would increase, and Natco's expected profits would consequently decline.

148. Upon the expiration of exclusivity, assuming normal competitive conditions, it is reasonable to expect that Natco would share the Revlimid market with 7 other generics at a price less than 20% of the brand price. Using the same monthly sales figure and gross profit margin used above, Natco would then expect to earn approximately \$9 million per month during the second six months after launch, or \$54 million dollars during that six-month period. Thus, under competitive conditions, Natco's anticipated profit during the first year after launch would be approximately \$538 million. Natco's profit would then remain steady at less than \$108 million per year.

149. A similar approach may be used to estimate Natco's profits as a result of its agreement with Celgene. While Natco's share of the market is capped at 7% during the first year after launch, the higher generic price more than offsets the restricted market share. Under the actual agreement, Natco was guaranteed 7% of the Revlimid market for a full year at a price very close to the branded price (say 90%). Thus, Natco could expect to earn approximately \$23.8 million per month starting in March 2022, or \$285.6 million from March 2022 through February 2023. Unlike the calculation assuming competitive conditions, Natco's expected profit goes up over time, not down. If we assume that Natco's share rises from 7% to 14% in the second year

(March 2023 through February 2024), Natco would earn \$571 million during that period.

Assuming another 7-point increase to 28% during the following third year (March 2024 through February 2025), and a limit of 33 1/3% from March 2025 to January 2026, Natco's expected profit from March 2024 to January 2026 totals \$2.48 billion (\$1.14 billion + \$1.34 billion), for a total expected profit of approximately \$3.34 billion during the period from March 2022 to January 2026.

150. By contrast, Natco's expected profit under competitive conditions is \$538 million during the first year (March 2022 through February 2023); \$108.7 million during the second year (March 2023 through February 2024); \$108.7 million during the third year (March 2024 through February 2025); and \$108.7 million during the final ten months (March 2025 through January 2026), for a total expected profit of \$864 million during the period from March 2022 to January 2026.

151. These figures are shown in tabular form below. As noted in the table, the present value (as of 2015) of the difference between Natco's expected profits under competitive conditions and its expected profits under its agreement with Celgene equals \$1.10 billion using a 10% discount rate. That is a reasonable estimate of the size of the payment from Celgene and BMS to Natco and Teva.

Time Period	Competitive Conditions	Volume-Limited License	Delta	PV as of 2015 @ 10%
First 180 days	\$484 million	\$142.8 million	(\$342 million)	(\$192.6 million)
Next 180 days	\$54 million	\$142.8 million	\$88 million	\$50 million
Year 2	\$108.7 million	\$571 million	\$463 million	\$237 million
Year 3	\$108.7 million	\$1.14 billion	\$1.03 billion	\$482 million
Year 4	\$108.7 million	\$1.34 billion	\$1.24 billion	\$525 million
TOTAL	\$864 million	\$3.34 billion	\$2.47 billion	\$1.10 billion

152. These calculations do not include an estimate of growth in the Revlimid market after March 2022; incorporating such an estimate would increase the size of the payment.

153. In addition to the enormous value given to Natco and Teva in the reverse-payment agreement, the reverse payment represented an economic sacrifice to Celgene at least equal to the profits it would have earned by launching its own NDA-based authorized generic under normal competitive conditions (approximately equal to what Natco would have expected to earn under competitive conditions). Of course, the profits Celgene earned by delaying generic competition until 2026 far outweighed that sacrifice.

E. Celgene Used Unlawful Deterrents and Enticements to Bring Other Manufacturers Into the Scheme.

154. Celgene's unlawful agreement with Natco set the stage for Celgene to forestall early entry by all manufacturers of generic Revlimid. That agreement created disincentives for second filers to litigate the Revlimid patents to conclusion, while leaving room for Celgene to pay them off with volume-limited licenses during the price-restricted period from September 2022 to January 2026. If any of these second filers succeeded, the entire market for Revlimid and its generic equivalents would become genericized—and, along with that, almost all of Celgene's Revlimid sales. Settling these patent challenges in a lawful manner based on the merits (or lack thereof) of Celgene's patent position would have resulted in no volume limitations and an agreed entry date markedly earlier than February 2026.

155. From March 2019 through July 2021, Celgene continued the anticompetitive scheme that the Celgene/Natco agreement contemplated and enabled. Specifically, Celgene made a series of anticompetitive reverse payments that the scheme envisioned.

156. Celgene's reverse payments created these periods of exclusivity and price protection for using sticks and carrots—overwhelming disincentives and massive enticements—to ensure that the second filers would not enter the market before or simultaneously with Natco. Celgene created the overwhelming disincentives by severely degrading both possibilities

(litigation and settlement) that Congress left open for second filers to enter the market before a first filer that, like Natco, settled for a very late entry date.

157. As noted in detail above, the Celgene/Natco restraints very substantially degraded the second filers' litigation pathway by ensuring that no second filer could enter the market before Natco. A second filer's success in invalidating the Revlimid patents would trigger Natco's entry into the market pursuant to the MFE, and possibly also entry of a Celgene authorized generic. And after waiting out Natco's 180-day ANDA Exclusivity Period, the second filer would also have likely been met with simultaneous entry by other second filers. With that number of generics in the market, the second filer could expect to garner only a small share of the generic units, at a price very substantially discounted off the brand price.

158. As noted in detail above, Celgene and Natco also very substantially degraded the second filers' settlement pathway by ensuring that no second filer would receive: (a) a license to enter the market under Celgene's NDA any time before February 1, 2026; (b) a license to enter under its own ANDA within 180 days of Natco's entry; and (c) a license to market a quantity greater than Natco's any time before February 1, 2026.

159. Celgene enticed the second filers not to undermine these restraints, paying each of them tens of millions of dollars. Having created the price-protected period September 2022 to January 31, 2026, Celgene gave to each of the second filers volume-limited, royalty-free license to sell certain quantities of generic Revlimid during that period. The restraints ensure that the price of generic Revlimid will stay very substantially above the competitive level during that time.

160. Those royalty-free licenses to sell in a price-protected market are worth tens of millions of dollars more to each of the second filers than they could have made by litigating their patent cases to conclusion and winning.

161. Celgene also paid each of the second filers by: (a) giving each of them an MFE; and (b) giving each of them an MFQ as to subsequently settling generic manufacturers.

162. Celgene's campaign of using sticks and carrots worked—each of the second filers identified below agreed to drop its challenge to Celgene's patents and stay out of the market until September 2022, and to “compete” in only the price-protected generic market from September 2022 to January 31, 2026.

163. As with the Celgene-Natco payments, Celgene's reverse payments to the other generic manufacturers do not increase overall output, significantly reduce price, or increase consumer choice. The payments merely substitute the generic manufacturers as the sellers of Revlimid units at near-brand-level prices, while preserving Celgene's massive monopoly profits. Individually and collectively, these agreements enact a classic market-allocation scheme. Had any one of the generic manufacturers defected from the conspiracy and refused to restrict output, Revlimid and its generic equivalents would be available to Plaintiffs and the Classes at lower prices, sooner.

1. Celgene Unlawfully Paid Lotus/Alvogen to Delay Generic Entry.

164. On September 6, 2017, Celgene brought suit against Lotus Pharmaceutical Co., Ltd. and Alvogen Pine Brook, LLC (collectively, “Alvogen”), in this Court, following receipt of Alvogen's paragraph IV certification notifying Celgene that it had filed ANDA No. 210480 with the FDA seeking approval to market generic Revlimid. Celgene alleged infringement of the 517,

‘720, ‘977, ‘784, ‘740, ‘800, ‘217, ‘569, ‘886, ‘717, ‘498, ‘531, ‘095, ‘120, ‘621, and ‘622 patents. *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842 (D.N.J.).

165. On July 10, 2018, a second suit was filed, asserting claims of infringement against Alvogen on the ‘357, ‘219, and ‘598 patents. *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:18-cv-11518 (D.N.J.). Notably, the ‘357, ‘219, and ‘598 patents asserted by Celgene had not been submitted to the Orange Book by Celgene in association with Revlimid as required under 21 U.S.C. § 355(b)(1) and attendant FDA regulations. Pursuant to these, Celgene was required to list any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its product with its NDA submission, or within thirty days for a new patent after the NDA had been submitted.

166. Alvogen filed answers to both complaints and counterclaimed that the patents asserted by Celgene were invalid, unenforceable, and noninfringed. Answer, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842, ECF No. 7 (D.N.J. Oct. 5, 2017). Answer, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:18-cv-11518, No. 8 (D.N.J. July 18, 2018). Celgene later filed a covenant not to sue on the ‘217 patent. Statement, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842, ECF No. 81 (D.N.J. Aug. 8, 2018).

167. In December 2018, the parties submitted a Joint Claim Construction Statement, in which Alvogen asserted that the methods-of-use patents for multiple myeloma (the ‘498 patent, ‘095 patent, ‘621 patent, and ‘622 patent) are invalid for, among other reasons, indefiniteness of key terms, which the parties agreed to address through expert discovery. *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842, ECF No. 92 (D.N.J. Dec. 17, 2018). A month later, the district court ordered mediation between the parties. Order, *Celgene Corp. v.*

Lotus Pharmaceutical Co., Ltd., et al., No. 2:17-cv-06842, ECF No. 99 (D.N.J. Jan. 14, 2019).

On February 22, 2019, Celgene and Lotus stipulated to bifurcating and staying all proceedings related to the REMS patents (the '720, '977, '784, '886, and '531 Patents), pending Celgene's appeal to the Federal Circuit of the PTAB's invalidation of the '720 Patent (ultimately affirmed on July 30, 2019). Stipulation, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842, ECF No. 105 81 (D.N.J. Feb. 22, 2019).

168. On March 29, 2019, Alvogen settled its lawsuits with Celgene, entering into an illegal reverse-payment agreement that will delay full generic competition until February 2026.

169. Under the Celgene-Alvogen agreement, Celgene has granted Lotus a license to sell a limited volume of generic Revlimid for a term beginning on September 1, 2022 and ending on January 31, 2026. The volume of generic Revlimid that Lotus is permitted to sell is limited to a low-single-digit percentage of Revlimid sales volume during the calendar year preceding the entry date of the Lotus generic. In effect, Celgene simply agreed to pay Lotus a share of its supracompetitive profits, which it maintained by engaging in the anticompetitive conduct described above.

170. In exchange for a share of Celgene's brand Revlimid revenue (via the volume-limited license), Alvogen agreed to abandon its challenge to Celgene's patents, to delay its entry into the market until September 2022, to "compete" in only the price-protected generic market from September 2022 to January 2026, and to delay unrestrained competition until February 2026.

171. When it entered into the Celgene-Alvogen agreement, Alvogen was aware of the arrangements between Celgene and Natco and knew all of the information in Paragraph 140 above regarding Celgene's settlements with later-settling generic manufacturers. Alvogen's

acceptance of the terms of the Celgene-Alvogen agreement made economic sense for Alvogen only because it knew that the Celgene-Natco agreement operated to restrain competition among Celgene, Natco, and second filers (like Alvogen) and to share among them the supracompetitive profits from Revlimid sales.

172. By entering into the Celgene-Alvogen agreement, Alvogen agreed to become part of the anticompetitive agreement to allocate the market for Revlimid and its generic equivalents. Along with the explicit market-allocation arrangements, the Celgene-Alvogen agreement also included an MFE, an MFQ, and a No-AG Payment, all of which facilitated the horizontal market allocation and helped ensure that no other second filer would gain earlier entry and upend the unlawful scheme.

173. The reverse payment from Celgene to Alvogen is objectively valued at more than a hundred million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

2. Celgene Unlawfully Paid Dr. Reddy's to Delay Generic Entry.

174. On October 20, 2016, Celgene brought suit against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"), in this Court, following receipt of Dr. Reddy's paragraph IV certification notifying Celgene that it had filed ANDA No. 209348 with the FDA seeking approval to market generic Revlimid. Celgene alleged infringement of the '800, '217, '569, '498, '095, '621, and '622 patents. *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd, et al.*, No. 2:16-cv-07704 (D.N.J).

175. Subsequent suits were filed on July 20, 2017, and April 12, 2018, against Dr. Reddy's asserting claims of infringement of the '740, '717, and '120 patents and of the 720, '977, '784, '886, and '531 patents, respectively. *Celgene Corp. v. Dr. Reddy's Laboratories,*

Ltd., et al., No. 2:17-cv-05314 (D.N.J.); *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 2:18-cv-06378 (D.N.J.).

176. Dr. Reddy's answered all three complaints, maintaining that the patents asserted by Celgene were not duly or lawfully issued. *See Answer, Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 2:16-cv-07704, ECF No. 7 (D.N.J. Nov. 18, 2016); Amended Answer, *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 2:17-cv-05314, ECF No. 17 (D.N.J. Oct. 18, 2017); Answer, *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 2:18-cv-06378, ECF No. 30 (D.N.J. May 31, 2018). And despite initially opposing Dr. Reddy's proposed claim construction, Celgene ultimately notified the Court that "the parties will not be filing responsive *Markman* briefs . . . and a *Markman* hearing will not be necessary." Letter, *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 2:16-cv-07704, ECF No. 77 (D.N.J. Mar. 23, 2016).¹⁹ This apparent concession to Dr. Reddy's construction of the Celgene's key polymorph patents ('800 and '217) paved the way for Dr. Reddy's to successfully argue that its ANDA did not infringe these patents because, were Celgene to oppose it (as it did in the Natco litigation), it would have subjected these patents to strong invalidity arguments.

177. On September 17, 2020, Dr. Reddy's settled its lawsuits with Celgene., entering into an illegal reverse-payment agreement that will delay full generic competition until February 2026.

178. Under the Celgene-Dr. Reddy's agreement, Celgene has granted Dr. Reddy's a license to sell a limited volume of generic Revlimid for a term beginning on September 1, 2022 and ending on January 31, 2026. The volume of generic Revlimid that Dr. Reddy's is permitted

¹⁹ Letter, *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 2:17-cv-05314, ECF No. 17 (D.N.J. Oct. 18, 2017); Letter, *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 2:18-cv-06378, ECF No. 30 (D.N.J. May 31, 2018).

to sell is limited to a low-single-digit percentage of Revlimid sales volume during the calendar year preceding the entry date of the Dr. Reddy's generic. In effect, Celgene simply agreed to pay Dr. Reddy's a share of the supracompetitive profits, which it maintained by engaging in the anticompetitive conduct described above.

179. In exchange for a share of Celgene's brand Revlimid revenue (via the volume-limited license), Dr. Reddy's agreed to abandon its challenge to Celgene's patents, to delay its entry into the market until September 2022, to "compete" in only the price-protected generic market from September 2022 to January 2026, and to delay unrestrained competition until February 2026.

180. When it entered into the Celgene-Dr. Reddy's agreement, Dr. Reddy's was aware of the arrangements between Celgene and Natco and knew all of the information in Paragraph 140 above regarding Celgene's settlements with later-settling generic manufacturers. Dr. Reddy's acceptance of the terms of the Celgene-Dr. Reddy's agreement made economic sense for Dr. Reddy's only because it knew that the Celgene-Natco agreement operated to restrain competition among Celgene, Natco, and second filers (like Dr. Reddy's) and to share among them the supracompetitive profits from Revlimid sales.

181. By entering into the Celgene-Dr. Reddy's agreement, Dr. Reddy's agreed to become part of the anticompetitive agreement to allocate the market for Revlimid and its generic equivalents. Along with the explicit market-allocation arrangements, the Celgene-Dr. Reddy's agreement also included an MFE, an MFQ, and a No-AG Payment, all of which facilitated the horizontal market allocation and helped ensure that no other second filer would gain earlier entry and upend the unlawful scheme.

182. The reverse payment from Celgene to Dr. Reddy's is objectively valued at more than a hundred million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

3. Celgene Unlawfully Paid Cipla to Delay Generic Entry.

183. On August 15, 2016, Celgene brought suit against Cipla, Ltd. ("Cipla"), in this Court, following receipt of Cipla's paragraph IV certification notifying Celgene that it had filed ANDA No. 210435 with the FDA seeking approval to market generic Revlimid. Celgene alleged infringement of the 800, '217, '569, '498, '095, '621, and '622 patents. *Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163 (D.N.J.).

184. On May 8, 2018, a second suit was filed, asserting claims of infringement against Cipla on the 357, '219, and '598 patents. *Celgene Corp. v. Cipla., Ltd., et al.*, No. 2:18-cv-08964 (D.N.J.). Notably, the '357, '219, and '598 patents asserted by Celgene had not been submitted to the Orange Book by Celgene in association with Revlimid as required under 21 U.S.C. § 355(b)(1) and attendant FDA regulations. Pursuant to these, Celgene was required to list any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its product with its NDA submission, or within thirty days for a new patent after the NDA had been submitted.

185. Subsequent to a second ANDA application filed by Cipla, Celgene brought a third suit on July 3, 2019, that added allegations of infringement of patents '740, '717, and '120. *Celgene Corp. v. Cipla., Ltd., et al.*, No. 2:19-cv-14731 (D.N.J.). Finally, a fourth suit was brought against Cipla on June 24, 2020, following Cipla's third ANDA application (for 2.5mg generic product), alleging infringement of the 740, '800, '569, '717, '498, '095, '120, '621, '622, and '217 patents. *Celgene Corp. v. Cipla., Ltd., et al.*, No. 2:20-cv-07759 (D.N.J.).

186. Cipla filed answers and counterclaims in all actions, alleging that the patents asserted by Celgene were invalid, unenforceable, and un infringed.²⁰ *See Answer, Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163, ECF No. 10 (D.N.J. October 13, 2017); Answer and Counterclaim, *Celgene Corp. v. Cipla., Ltd., et al.*, No. 2:18-cv-08964, ECF No. 9 (D.N.J. July 16, 2018); Answer and Counterclaim, *Celgene Corp. v. Cipla., Ltd., et al.*, No. 2:19-cv-14731, ECF No. 11 (D.N.J. August 26, 2019). Celgene later filed a covenant not to sue on the ‘217 patent. Statement, *Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163, ECF No. 61 (D.N.J. Aug. 8, 2018); *see also Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731, ECF No. 75 (D.N.J. July 13, 2020). The parties submitted a Joint Claim Construction and Prehearing Statement in May 2020, notifying the Court that there were no disputes as to claim construction. *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731, ECF No. 63 (D.N.J. May 28, 2020).

187. On December 11, 2020, Cipla settled its lawsuits with Celgene, entering into an illegal reverse-payment agreement that will delay full generic competition until February 2026.

188. Under the Celgene-Cipla agreement, Celgene has granted Cipla a license to sell a limited volume of generic Revlimid for a term beginning September 1, 2022 and ending on February 1, 2026. The volume of generic Revlimid that Cipla is permitted to sell is limited to a low-single-digit percentage of Revlimid sales volume during the calendar year preceding the entry date of the Cipla generic. In effect, Celgene simply agreed to pay to Cipla a share of supracompetitive profits, which it maintained by engaging in the anticompetitive conduct described above.

²⁰ On June 8, 2020, Civil Action Nos. 18-cv-08964 and 17-cv-06163 were administratively terminated and incorporated by reference into Civil Action No. 19-cv-14731.

189. In exchange for a share of Celgene's brand Revlimid revenue (via the volume-limited license), Cipla agreed to abandon its challenge to Celgene's patents, to delay its entry into the market until September 2022, to "compete" in only the price-protected generic market from September 2022 to January 2026, and to delay unrestrained competition until February 2026.

190. When it entered into the Celgene-Cipla agreement, Cipla was aware of the arrangements between Celgene and Natco and knew all of the information in Paragraph 140 above regarding Celgene's settlements with later-settling generic manufacturers. Cipla's acceptance of the terms of the Celgene-Cipla agreement made economic sense for Cipla only because it knew that the Celgene-Natco agreement operated to restrain competition among Celgene, Natco, and second filers (like Cipla) and to share among them the supracompetitive profits from Revlimid sales.

191. By entering into the Celgene-Cipla agreement, Cipla agreed to become part of the anticompetitive agreement to allocate the market for Revlimid and its generic equivalents. Along with the explicit market-allocation arrangements, the Celgene-Cipla agreement also included an MFE, an MFQ, and a No-AG Payment, all of which facilitated the horizontal market allocation and helped ensure that no other second filer would gain earlier entry and upend the unlawful scheme.

192. The reverse payment from Celgene to Cipla is objectively valued at more than a hundred million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

4. Celgene Unlawfully Paid Apotex to Delay Generic Entry.

193. On January 11, 2018, Celgene brought suit against Apotex, Inc. (“Apotex”), in this Court, following receipt of Apotex’s paragraph IV certification notifying Celgene that it had filed ANDA No. 211022 with the FDA seeking approval to market generic Revlimid. Celgene alleged infringement of the ‘720, ‘977, ‘784, ‘886, ‘531, ‘800, ‘217, ‘363, and ‘929 patents. *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461(D.N.J.).

194. Subsequent suits were filed on February 26, 2019 and June 19, 2019, asserting claims of infringement against Apotex on the 740, ‘717, and ‘120 patents and on the ‘357, ‘219, and ‘598 patents, respectively. *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-06999 (D.N.J.); *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-13994 (D.N.J.). Notably, the ‘357, ‘219, and ‘598 patents asserted by Celgene had not been submitted to the Orange Book by Celgene in association with Revlimid as required under 21 U.S.C. § 355(b)(1) and attendant FDA regulations. Pursuant to these, Celgene was required to list any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its product with its NDA submission, or within thirty days for a new patent after the NDA had been submitted.

195. Apotex filed answers to these complaints and asserted affirmative defenses alleging that the patents asserted by Celgene were invalid, unenforceable, and noninfringed. Answer, *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461, ECF No. 45 (D.N.J. Aug. 30, 2018). Answer, *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-06999, ECF No. 9 (D.N.J. Apr. 2, 2019); Answer, *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-13994, ECF No. 9 (D.N.J. July 25, 2019). Celgene later filed a covenant not to sue on the ‘217 patent. Statement, *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461, ECF No. 58 (D.N.J. Jan. 22, 2019).

196. Celgene later filed a covenant not to sue on the '217 patent. Statement, *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461, ECF No. 58 (D.N.J. Jan. 22, 2019). A few months later, the Court entered a judgment of non-infringement in favor of Apotex and against Celgene as to the '217 patent. Consent Judgment, *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461, ECF No. 63 (D.N.J. Apr. 30, 2019). The following week, the Court issued an order subsequent to the parties' stipulation bifurcating and staying all proceedings related to the REMS patents (the '720, '977, '784, '886, and '531 Patents), pending Celgene's appeal to the Federal Circuit of the PTAB's invalidation of the '720 Patent (ultimately affirmed on July 30, 2019). Stipulation and Order, *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461, ECF No. 65 (D.N.J. May 8, 2019).

197. In the subsequent suits Celgene filed against Apotex, the parties submitted a joint claim construction statement informing the Court that there were no claim terms in dispute and no need for a *Markham* hearing. Letter, *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-06999, ECF No. 43 (D.N.J. Dec. 2, 2019); Statement, *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-13994, ECF No. (D.N.J. Feb. 27, 2020).

198. On March 10, 2021, Apotex settled its lawsuits with Celgene, entering into an illegal reverse payment agreement that will delay full generic competition until February 2026.

199. Under the Celgene-Apotex agreement, Celgene has granted Apotex a license to sell a limited volume of generic Revlimid for a term beginning on September 1, 2022 and ending on January 31, 2026. The volume of generic Revlimid that Apotex is permitted to sell is limited to a low-single-digit percentage of Revlimid sales volume during the calendar year preceding the entry date of the Apotex generic. In effect, Celgene simply agreed to pay Apotex a share of its supracompetitive profits, which it maintained by engaging in the anticompetitive conduct described above.

200. In exchange for a share of Celgene's brand Revlimid revenue (via the volume-limited license), Apotex agreed to abandon its challenge to Celgene's patents, to delay its entry into the market until September 2022, to "compete" in only the price-protected generic market from September 2022 to January 2026, and to delay unrestrained competition until February 2026.

201. When it entered into the Celgene-Apotex agreement, Apotex was aware of the arrangements between Celgene and Natco and knew all of the information in Paragraph 140 above regarding Celgene's settlements with later-settling generic manufacturers. Apotex's acceptance of the terms of the Celgene-Apotex agreement made economic sense for Apotex only because it knew that the Celgene-Natco agreement operated to restrain competition among Celgene, Natco, and second filers (like Apotex) and to share among them the supracompetitive profits from Revlimid sales.

202. By entering into the Celgene-Apotex agreement, Apotex agreed to become part of the anticompetitive agreement to allocate the market for Revlimid and its generic equivalents. Along with the explicit market-allocation arrangements, the Celgene-Apotex agreement also included an MFE, an MFQ, and a No-AG Payment, all of which facilitated the horizontal market allocation and helped ensure that no other second filer would gain earlier entry and upend the unlawful scheme.

203. The reverse payment from Celgene to Apotex is objectively valued at more than a hundred million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

5. Celgene Unlawfully Paid Zydus to Delay Generic Entry.

204. On April 12, 2017, Celgene brought suit against Zydus Pharmaceuticals (USA) Inc., Zydus International Pvt. Ltd, and Cadila Healthcare Ltd., (collectively, “Zydus”), in this Court, following receipt of Zydus’s paragraph IV certification notifying Celgene that it had filed ANDA No. 210154 with the FDA seeking approval to market generic Revlimid. Celgene alleged infringement of the 800, ‘217, ‘569, ‘498, ‘095, ‘621, and ‘622 patents. *Celgene Corp. v. Zydus Pharmaceutical (USA) Inc., et al.*, No. 2:17-cv-02528 (D.N.J.).

205. On April 27, 2019, a second suit was filed, asserting claims of infringement against Zydus on the 357, ‘219, and ‘598 patents. *Celgene Corp. v. Zydus Pharmaceutical (USA) Inc., et al.*, No. 2:18-cv-08519 (D.N.J.). Notably, the patents asserted by Celgene in this suit had not been submitted to the Orange Book by Celgene in association with Revlimid as required under 21 U.S.C. § 355(b)(1) and attendant FDA regulations. Pursuant to these, Celgene was required to list any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its product with its NDA submission, or within thirty days for a new patent after the NDA had been submitted.

206. Zydus filed answers to both complaints and counterclaimed that the patents asserted by Celgene were invalid, unenforceable, and noninfringed. Answer, *Celgene Corp. v. Zydus Pharmaceutical (USA) Inc., et al.*, No. 2:17-cv-02528, ECF No. 19 (D.N.J. Aug. 7, 2017); Answer, *Celgene Corp. v. Zydus Pharmaceutical (USA) Inc., et al.*, No. 2:18-cv-08519, ECF No. 10 (D.N.J. July 9, 2018). Celgene later filed a covenant not to sue on the ‘217 patent. Statement, *Celgene Corp. v. Zydus Pharmaceutical (USA) Inc., et al.*, No. 2:17-cv-02528, ECF No. 93 (D.N.J. Aug. 8, 2018).

207. The parties filed a Joint Claim Construction and Prehearing Statement in December 2018 informing the Court that there were “no disputes for purposes of *Markman*” and

thus “no need for a *Markham* hearing.” Joint Statement, *Celgene Corp. v. Zydus Pharmaceutical (USA) Inc., et al.*, No. 2:17-cv-02528, ECF No. 111 (D.N.J. Dec. 17, 2018). A month later, the district court ordered mediation between the parties. Order, *Celgene Corp. v. Zydus Pharmaceutical (USA) Inc., et al.*, No. 2:17-cv-02528, ECF No. 117 (D.N.J. Jan. 14, 2019).

208. On March 24, 2021, Zydus settled its lawsuits with Celgene, entering into an illegal reverse-payment agreement that will delay full generic competition until February 2026.

209. Under the Celgene-Zydus agreement, Celgene has granted Zydus a license to sell a limited volume of generic Revlimid for a term beginning on September 1, 2022 and ending on January 31, 2026. The volume of generic Revlimid that Zydus is permitted to sell is limited to a low-single-digit percentage of Revlimid sales volume during the calendar year preceding the entry date of the Zydus generic. In effect, Celgene simply agreed to pay Zydus a share of its supracompetitive profits, which it maintained by engaging in the anticompetitive conduct described above.

210. In exchange for a share of Celgene’s brand Revlimid revenue (via the volume-limited license), Zydus agreed to abandon its challenge to Celgene’s patents, to delay its entry into the market until September 2022, to “compete” in only the price-protected generic market from September 2022 to January 2026, and to delay unrestrained competition until February 2026.

211. When it entered into the Celgene-Zydus agreement, Zydus was aware of the arrangements between Celgene and Natco and knew all of the information in Paragraph 140 above regarding Celgene’s settlements with later-settling generic manufacturers. Zydus’s acceptance of the terms of the Celgene-Zydus agreement made economic sense for Zydus only because it knew that the Celgene-Natco agreement operated to restrain competition among

Celgene, Natco, and second filers (like Zydus) and to share among them the supracompetitive profits from Revlimid sales.

212. By entering into the Celgene-Zydus agreement, Zydus agreed to become part of the anticompetitive agreement to allocate the market for Revlimid and its generic equivalents. Along with the explicit market-allocation arrangements, the Celgene-Zydus agreement also included an MFE, an MFQ, and a No-AG Payment, all of which facilitated the horizontal market allocation and helped ensure that no other second filer would gain earlier entry and upend the unlawful scheme.

213. The reverse payment from Celgene to Zydus is objectively valued at more than a hundred million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

6. Celgene Unlawfully Paid Mylan to Delay Generic Entry.

214. On December 31, 2019, Celgene brought suit against Mylan Pharmaceutical Inc., Mylan Inc., and Mylan N.V. (collectively, “Mylan”), in this Court, following receipt of Mylan’s paragraph IV certification notifying Celgene that it had filed ANDA No. 213912 with the FDA seeking approval to market generic Revlimid. Celgene alleged infringement of the ‘730, ‘800, ‘217, ‘569, ‘717, ‘498, ‘095, ‘120, ‘621, and ‘622 patents. *Celgene Corp. v. Mylan Pharmaceuticals, Inc., et al.*, No. 2:19-cv-22231-SDW-LDW (D.N.J.). A second—identical—suit was filed on January 3, 2020, in the Northern District of West Virginia. *Celgene Corp. v. Mylan Pharmaceuticals, Inc., et al.*, No. 2:20-cv-00003 (N.D. W.Va.).

215. Mylan filed an answer and counterclaimed that the patents asserted by Celgene were invalid, unenforceable, and noninfringed. Answer, *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:20-cv-00003, ECF No. 26 (N.D. W.Va. Apr. 15, 2020).

Celgene later filed a covenant not to sue on the ‘217 patent. Statement, *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:20-cv-00003, ECF No. 120 (N.D. W.Va. Oct. 9, 2020).

216. Celgene filed an amended complaint on November 4, 2020 that was answered by Mylan two weeks later. Answer, *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:20-cv-00003, ECF No. 112 (N.D. W.Va. Sept. 4, 2020). The parties submitted a Joint Claim Construction and Prehearing Statement two months later notifying the court that there were no disputes as to claim construction. *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:20-cv-00003, ECF No. 138 (N.D. W.Va. Nov. 16, 2020).

217. On July 23, 2021, Mylan settled its lawsuit with Celgene, entering into an illegal reverse payment agreement that will delay full generic competition until February 2026.

218. Under the Celgene-Mylan agreement, Celgene has granted Mylan a license to sell a limited volume of generic Revlimid for a term beginning on September 1, 2022 and ending on January 31, 2026. The volume of generic Revlimid that Mylan is permitted to sell is limited to a low-single-digit percentage of Revlimid sales volume during the calendar year preceding the entry date of the Mylan generic. In effect, Celgene simply agreed to pay Mylan a share of its supracompetitive profits, which it maintained by engaging in the anticompetitive conduct described above.

219. In exchange for a share of Celgene’s brand Revlimid revenue (via the volume-limited license), Mylan agreed to abandon its challenge to Celgene’s patents, to delay its entry into the market until September 2022, to “compete” in only the price-protected generic market from September 2022 to January 2026, and to delay unrestrained competition until February 2026.

220. When it entered into the Celgene-Mylan agreement, Mylan was aware of the arrangements between Celgene and Natco and knew all of the information in Paragraph 140 above regarding Celgene's settlements with later-settling generic manufacturers. Mylan's acceptance of the terms of the Celgene-Mylan agreement made economic sense for Mylan only because it knew that the Celgene-Natco agreement operated to restrain competition among Celgene, Natco, and second filers (like Mylan) and to share among them the supracompetitive profits from Revlimid sales.

221. By entering into the Celgene-Mylan agreement, Mylan agreed to become part of the anticompetitive agreement to allocate the market for Revlimid and its generic equivalents. Along with the explicit market-allocation arrangements, the Celgene-Mylan agreement also included an MFE, an MFQ, and a No-AG Payment, all of which facilitated the horizontal market allocation and helped ensure that no other second filer would gain earlier entry and upend the unlawful scheme.

222. The reverse payment from Celgene to Mylan is objectively valued at more than a hundred million dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

F. Absent the Unlawful Conduct, Unrestrained Generic Entry Would Have Occurred Sooner.

223. Absent the unlawful reverse payment, a reasonable generic company in the position of Natco would have launched generic Revlimid 5mg, 10mg, 15mg, and 25mg earlier either: (i) at-risk; (ii) after litigating victoriously; or (iii) under license from Celgene. At the very latest, absent the unlawful reverse payments, Natco would have launched without restraints on May 21, 2021, after receiving final approval from the FDA.

224. Further, the FDA approvals of Apotex, Cipla, Dr. Reddy's, Lotus, Mylan, and Zydus for 5mg, 10mg, 15mg, and 25mg were bottlenecked behind Natco's 180-day ANDA Exclusivity Period. When Natco's 180-day ANDA Exclusivity Period expired, they all would have received FDA approval and launched generic Revlimid. Absent the unlawful reverse payments, Natco would have launched earlier, and thus its 180-day ANDA Exclusivity Period would have expired earlier, resulting in earlier FDA approval and launches of Apotex, Cipla, Dr. Reddy's, Lotus, Mylan, and Zydus.

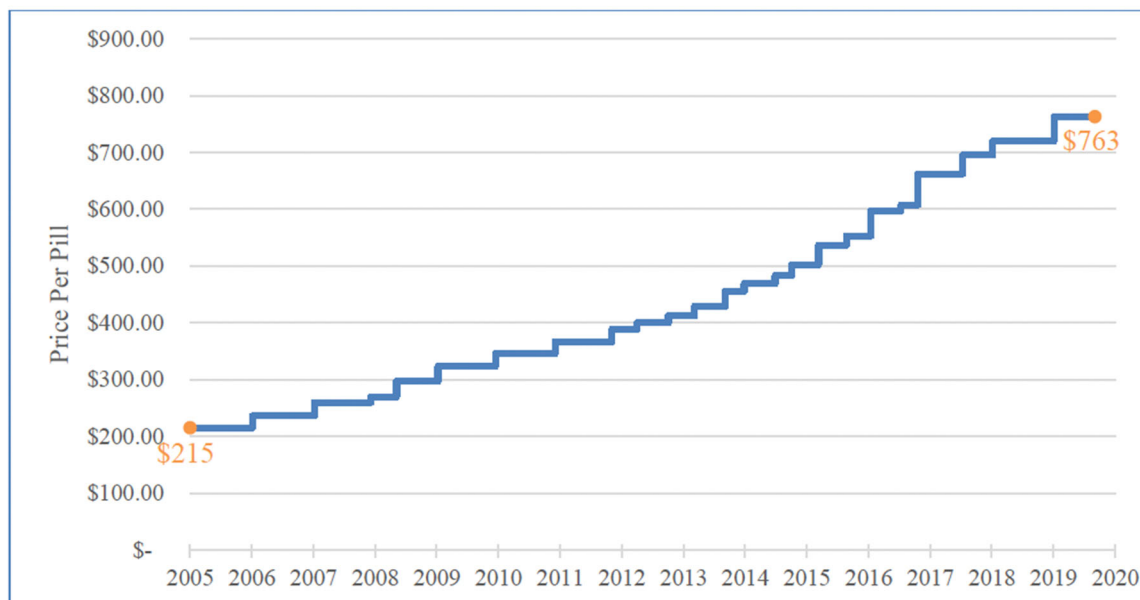
225. Moreover, absent the unlawful reverse payments to Apotex, Cipla, Dr. Reddy's, Lotus, Mylan, and Zydus, they would have launched earlier than they did, either: (i) at-risk; (ii) after litigating victoriously; or (iii) under license from Celgene.

226. As above, absent the unlawful reverse payment, a reasonable generic company in the position of Dr. Reddy's would have been able to launch generic Revlimid 2.5mg and 20mg earlier either: (i) at-risk; (ii) after litigating victoriously; or (iii) under license from Celgene. At the very latest, Dr. Reddy's would have received final approval on October 14, 2021 or, in the absence of the reverse payment, even earlier.

227. Further, as of the filing of this Amended Class Action Complaint, Dr. Reddy's 180-day ANDA Exclusivity Period for the 2.5mg and 20mg strengths has yet to expire, and so additional manufacturers of generic Revlimid 2.5mg and 20mg have yet to receive FDA approval and launch. Absent the unlawful reverse payment, Dr. Reddy's would have launched earlier, and thus its 180-day ANDA Exclusivity Period would have expired earlier, resulting in the earlier FDA approval and launch of generic Revlimid 2.5mg and 20mg by additional generic competitors.

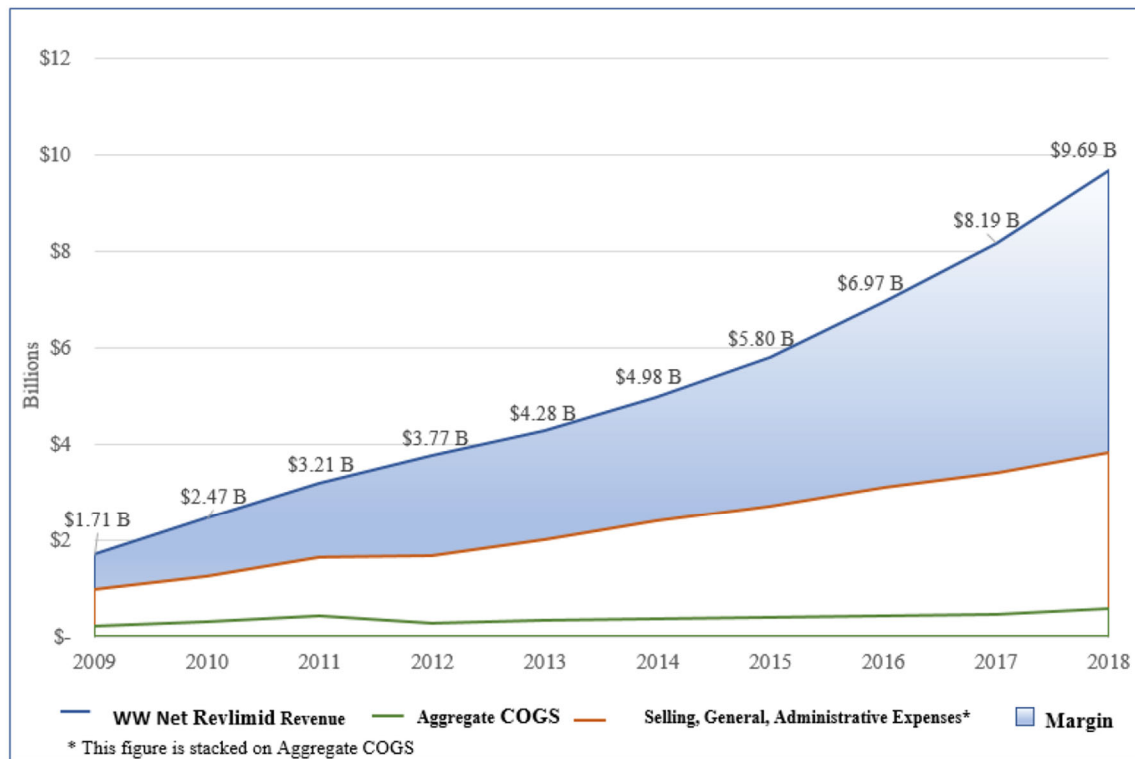
G. Defendants Fully Exploited the Monopoly They Created.

228. After its launch in 2005, Celgene raised the price of Revlimid 22 times—from \$215 per pill to \$719 per pill in 2019. Upon acquiring Celgene and the exclusive right to manufacture and sell Revlimid in November 2019, BMS immediately increased the price to \$763 per pill and has continued to implement steady price increases. As of November 2022, Revlimid is \$877 per pill. A monthly regimen of 15mg, 20mg or 25mg Revlimid requires 21 pills, resulting in an annual cost of \$221,215 per person at these doses. A monthly regimen of 2.5mg, 5mg, or 10mg Revlimid requires 28 pills, resulting in an annual cost of \$294,915 per person at these doses. The following chart shows Revlimid’s price-per-pill for the period from 2005 through the end of 2019:



U.S. House Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigations: Celgene and Bristol-Myers Squibb—Revlimid* (Sept. 30, 2020 at pg. 1).

229. The price increases were completely detached from production costs (cost of goods sold, “COGS”), which remained stable, and far outpaced Celgene’s other expenses:



U.S. House Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigations: Celgene and Bristol-Myers Squibb—Revlimid* (Sept. 30, 2020 at pg. 35).

230. Celgene’s price hikes also cannot be attributed to research and development (R&D) costs because the development of Revlimid as a treatment for multiple myeloma was largely backed by taxpayer-funded research. In 1993, researchers at Boston Children’s Hospital (“BCH”) realized that thalidomide and its chemical analog EM-12—the compound Celgene would eventually name Revlimid—could prevent tumor growth. The BCH scientists convinced researchers at the University of Arkansas Medical Center to conduct a larger study, funded by a \$2.3 million grant from the National Institutes of Health (NIH), which proved thalidomide’s efficacy in treating multiple myeloma. It was only after this publicly funded study was published in 1999—and Celgene’s revenue for thalidomide rose—that Celgene decided to conduct the research needed to acquire FDA approval for thalidomide as a multiple myeloma treatment.

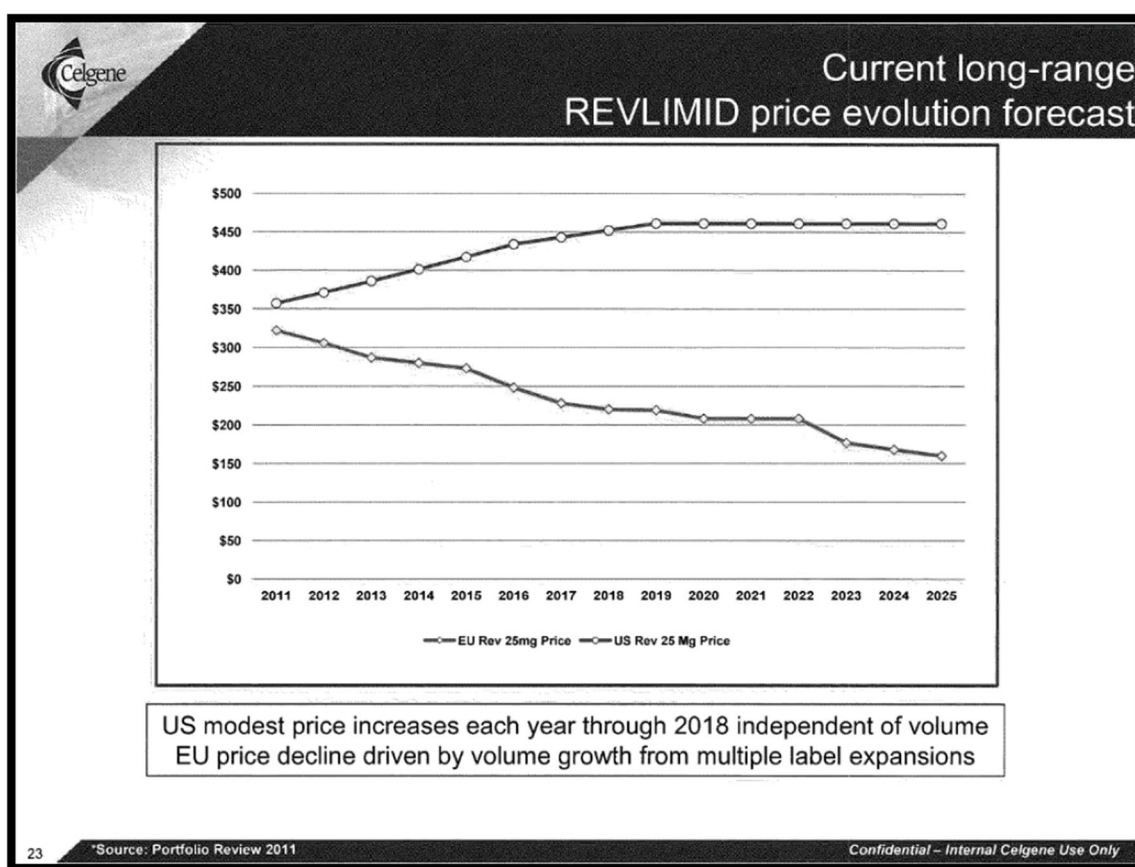
231. The NIH later provided over \$4 million to the Dana Farber Cancer Institute to conduct the studies that showed Revlimid's compound was more effective than thalidomide in treating relapsed multiple myeloma patients. It then contributed nearly \$300,000 to the Mayo Clinic and more than \$70 million to the Eastern Cooperative Oncology Group (ECOG) to conduct the research showing Revlimid could successfully treat newly diagnosed multiple myeloma patients. It also gave over \$80 million to the Alliance for Clinical Trials in Oncology for a study showing Revlimid extended the survival of patients who had received stem cell transplants.

232. Time and time again, it was only after taxpayer-funded research proved Revlimid's efficacy for each new segment of the multiple myeloma patient population that Celgene decided to invest in clinical trials that were virtually guaranteed to succeed and lead to FDA approval for the new uses. For instance, an April 2009 company memo relied on the \$70 million NIH-funded ECOG study in noting that the newly diagnosed patient population was "the largest commercial opportunity for the multiple myeloma franchise," with an estimated net value of almost \$1.5 billion and a 114% rate of return. The R&D investments Celgene did make to obtain FDA approval for Revlimid's various indications were essentially risk-free and guaranteed to be massively lucrative.

233. Despite benefitting from over \$150 million in taxpayer-funded cancer research, Celgene intentionally hampered studies by competitors that could have led to new advancements in cancer treatment. Internal company communications reveal a refusal to provide discounted Revlimid to researchers at other pharmaceutical companies, forcing them to pay hundreds of millions of dollars per year for the drug. In discussing one company's request for a discount, one Celgene executive wrote, "Anything we can do to hamper their development would help."

Another stated that discounting decisions “should be based on benefit to Celgene and strategic fit” and that “development capacity or lack thereof . . . is [the competitor’s] issue to deal with.”

234. Celgene did not always plan to exploit Revlimid’s pricing potential as aggressively as it has. Although Celgene’s price increases drove Revlimid’s price-per-pill up to \$719 by 2019, a June 2013 board presentation forecasted that “modest price increases” that were “independent of volume” would raise Revlimid’s price-per-pill to just above \$450 by 2019, where it would stabilize and remain through 2025:



235. During a 2015 deposition, Celgene’s former Senior Vice President of Sales and Marketing stated that the company’s executives could raise Revlimid’s price “any time they

wanted.”²¹ And they did. For example, in response to lower-than-expected revenue from Revlimid in the first quarter of 2014, Celgene’s then-Executive Vice President (and future CEO) proposed an immediate 4% price increase in lieu of a 3% increase that was planned for the following month. The more immediate, more significant price increase was projected to yield incremental net sales of \$24.8 million during the remainder of 2014. Celgene’s Corporate Market Access Committee approved the price increase, and it took effect that evening.

236. Celgene used price increases not only to compensate for missed sales goals, but also to implement aggressive new ones. Between January 2017 and January 2019, Celgene increased the cost of Revlimid by 30%, allowing it to nearly meet its \$8 billion annual revenue goal two years ahead of schedule. Of Celgene’s \$7.8 billion in U.S. revenue in 2018, \$6.46 billion came from sales of Revlimid.

237. Celgene’s net revenue from U.S. sales of Revlimid increased from \$1 billion in 2009 to \$6.46 billion in 2018. This generated a quintupling of the company’s annual profits in this same time period—from \$780 million to \$4 billion. Between 2009 and 2018, Celgene extracted \$32 billion in net revenue from U.S. sales of Revlimid.

238. Celgene executives benefitted handsomely from the explosion in Revlimid’s price and revenue. The company’s top executives were paid over \$400 million between 2006 and 2017, including performance bonuses that were, at times, triple or quadruple executives’ base salaries. For example, in 2016, Celgene’s Chairman received a performance bonus of over \$6 million, and its CEO received a performance bonus of over \$3.6 million.

²¹ Deposition of Francis V. Brown, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D.N.J.) (Dec. 2, 2015).

Celgene Senior Executive Compensation					
	2016				
	Base Salary	Stock & Option Awards	Performance Bonuses	All Other Compensation	Total
Robert Hugin, Chairman	\$ 1,500,000	\$ 8,484,785	\$ 6,294,053	\$ 247,399	\$ 16,526,237
Mark Alles, CEO	\$ 1,062,583	\$ 7,421,846	\$ 3,689,654	\$ 18,334	\$ 12,192,417
Peter Kellogg, EVP, CFO	\$ 845,667	\$ 4,554,018	\$ 2,707,912	\$ 29,677	\$ 8,137,274
Jacquelyn Fouse, Strategic Advisor	\$ 941,633	\$ 4,745,875	\$ 3,222,523	\$ 109,784	\$ 9,019,815
Scott Smith, President, COO	\$ 691,667	\$ 4,455,762	\$ 1,296,827	\$ 19,541	\$ 6,463,797
Rupert Vessey, President, R&ED	\$ 673,141	\$ 3,159,174	\$ 1,063,826	\$ 23,850	\$ 4,919,991
Total Executives					\$ 57,259,531
	2017				
	Base Salary	Stock & Option Awards	Performance Bonuses	All Other Compensation	Total
Robert Hugin, Chairman	\$ 1,500,000	\$ 8,034,415	\$ 2,175,000	\$ 245,322	\$ 11,954,737
Mark Alles, CEO	\$ 1,266,667	\$ 9,687,923	\$ 2,144,623	\$ 16,772	\$ 13,115,985
Peter Kellogg, EVP, CFO	\$ 871,250	\$ 4,735,720	\$ 800,352	\$ 28,196	\$ 6,435,518
Scott Smith, President, COO	\$ 833,000	\$ 4,966,932	\$ 845,495	\$ 16,772	\$ 6,662,199
Rupert Vessey, President, R&ED	\$ 691,917	\$ 4,092,179	\$ 957,442	\$ 25,359	\$ 5,766,897
Total Executives					\$ 43,935,336

Compensation Attributable to Revlimid U.S. Price Increases						
	2016			2017		
	MIP	LTIP	Total	MIP	LTIP	Total
Robert Hugin, Executive Chairman	\$ 187,500.03	\$ 202,180.75	\$ 389,680.79	\$ 337,500.00	\$ 287,097.24	\$ 624,597.24
Mark Alles, CEO	\$ 12,619.08	\$ 102,451.96	\$ 115,071.04	\$ 332,786.33	\$ 60,548.73	\$ 393,335.05
Peter Kellogg, EVP, CFO	\$ 62,731.54	\$ 104,132.66	\$ 166,864.20	\$ 124,192.55	\$ 60,548.73	\$ 184,741.28
Jacquelyn Fouse, Strategic Advisor	\$ 83,202.73	\$ 115,748.66	\$ 198,951.39	-	-	-
Scott Smith, President, COO	\$ 54,766.15	\$ 24,817.12	\$ 79,583.27	\$ 131,197.50	\$ 60,548.73	\$ 191,746.23
Rupert Vessey, President, R&ED	\$ 46,864.09	\$ 18,605.78	\$ 65,469.87	\$ 97,622.84		\$ 97,622.84
Total Executives			\$ 1,015,620.55			\$1,492,042.64

U.S. House Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigations: Celgene and Bristol-Myers Squibb—Revlimid* (Sept. 30, 2020 at pg. 9, 11).

239. Celgene's bonus formula was based heavily on the company meeting its annual revenue and earnings goals, which rose by billions every year and which were heavily dependent on Revlimid sales. For instance, in 2017, three price hikes on Revlimid resulted in \$600 million in increased revenue, causing Celgene to narrowly meet its \$13 billion net revenue goal—and its executives to narrowly make their full bonuses.

240. BMS's acquisition of Celgene—which would promptly raise the price of Revlimid by over 6%—was also very lucrative for Celgene executives. Just weeks before the acquisition, Celgene implemented a new Executive Severance Plan providing that top executives

would receive 2.5 to 3 times their annual salaries, plus other cash incentives and benefits, in the event that they were terminated or resigned as a result of the sale. CEO Mark Alles, for example, received more than \$28 million when he left the company after the transaction closed.

241. Revlimid's high profit margin and the absence of any generic competition were prime motivation for BMS's purchase of Celgene. Contemporaneous joint SEC filings concerning the acquisition acknowledged that "[a]ny such expiration or loss of patent protection with respect to REVLIMID® that occurs sooner than anticipated would be harmful to the combined company and could have a material adverse effect on its business, financial condition or results of operations."²²

VI. MARKET EFFECTS

242. By impeding competition from generic Revlimid, Defendants' anticompetitive conduct caused Plaintiffs and Class members to pay more than they would have otherwise paid for branded and generic Revlimid. Earlier entry of Natco's generic Revlimid would have given purchasers the choice between branded Revlimid and AB-rated generic substitutes of Revlimid, which are priced substantially below the brand price. A substantial majority of purchasers would have bought the lower-priced generic drugs rather than the higher-priced branded Revlimid. Every state has pharmacy substitution laws requiring or encouraging pharmacies to substitute AB-rated generics for branded prescription pharmaceuticals whenever possible. Absent the Defendants' anticompetitive conduct, Plaintiffs and other Class members would have saved billions of dollars by paying less for branded Revlimid and by being able to purchase generic

²² Bristol-Myers Squibb Company and Celgene Corporation, 2019 Joint Proxy Statement (Feb. 22, 2019) (online at www.sec.gov/Archives/edgar/data/816284/000114036119003696/s002620x7_defm14a.htm).

Revlimid earlier. Defendants' anticompetitive conduct caused Plaintiffs and other Class members to incur overcharges on their purchases of both branded and generic Revlimid.

243. Absent the Defendants' anticompetitive conduct, immediately upon Natco's entry into the market, Celgene, as a rational economic actor seeking to recoup lost branded sales, would have entered the market with its own authorized generic version of Revlimid in competition with Natco's generic. That is exactly what Celgene has done, historically, when it has faced new, unrestrained generic competition with one of its lucrative brand drugs, including in the case of Focalin XR and Vidaza.

244. The unlawful MFE, MFEP, and MFQ in the Celgene-Natco agreement compounded the No-AG Payment's anticompetitive effects. The MFE, MFEP, and MFQ prevented second filers from undoing the delay in generic entry. Those anticompetitive clauses undermined the incentives that Congress provided to encourage second filers to try to enter the market before Natco's agreed entry date in March 2022. Absent the unlawful restraints, second filers would have entered the market much sooner than they did. The restraints caused Plaintiffs and other Class members to incur overcharges on their purchases of both branded and generic Revlimid.

245. Defendants' anticompetitive conduct created and extended the Revlimid monopoly. As a result of the delay, only Celgene's brand product was available until March 2022. Celgene fully exploited that monopoly, as is evidenced by its consistent and exorbitant price increases. Absent the Defendants' unlawful conduct, Natco would have entered the market, at the latest, in or about May 2021, when the price for a 30-day supply of 15mg, 20mg, and 25mg brand Revlimid was about \$17,490 and the price for a 30-day supply of 5mg and 10mg brand Revlimid was about \$23,317. Generic competition would have driven the price

down to, at most, \$800 for a 30-day supply. Therefore, as a result of the Defendants' anticompetitive conduct, the actual price for Revlimid was more than 21 times greater than it would have been under competitive conditions.

246. Defendants' unlawful conduct also harmed Plaintiffs and Class members by increasing the prices charged by Revlimid generics. When entering a market, generic manufacturers price their products based on a percentage discount off of the then-prevailing brand price. Absent the Defendants' unlawful conduct, the generics would have entered no later than May 2021, when the price for a 30-day supply of 15mg, 20mg, and 25mg brand Revlimid was about \$17,490 and the price for a 30-day supply of 5mg and 10mg brand Revlimid was about \$23,317. Thus, Defendants' unlawful conduct has caused Plaintiffs and Class members to pay substantial overcharges on their purchases of generic Revlimid, beginning in March 2022 and continuing until today.

VII. MARKET POWER

247. At all relevant times, Defendants had market power over Revlimid and its generic equivalents. The Defendants had the power to maintain the prices of those drugs at supracompetitive levels without losing sufficient sales to other products to make the supracompetitive prices unprofitable.

248. A small but significant, non-transitory increase in the price of Revlimid and its generic equivalents, above the competitive level, did not cause a significant loss of sales to any other product. At competitive prices, Revlimid and its generic equivalents do not exhibit significant, positive cross-elasticity of demand, with respect to price, as to any other product or treatment for multiple myeloma.

249. Direct evidence of Defendants' market power includes the following: (a) absent Defendants' unlawful conduct, generic Revlimid would have entered the market much earlier and at a substantial discount to brand Revlimid; (b) when generic Revlimid eventually entered the market, the amount that the generic manufacturers were permitted to manufacture and sell was volume-limited; (c) Celgene's gross margin on Revlimid (including the costs of ongoing research/development, marketing, selling, and administrative expenses) steadily rose from around 100% in 2009 to almost 350% by 2018; (d) as revealed by internal company documents, Celgene kept the price of Revlimid astronomically high with the specific intent to inhibit generic drug companies' ability to obtain the samples needed to develop their own AB-rated generics; (e) Celgene never lost Revlimid sales or lowered the price of Revlimid to the competitive level in response to the pricing of other brand or generic drugs ; (f) from 2005 to 2022, Celgene profitably raised the price of Revlimid by more than \$500.

250. Celgene's power to profitably raise the price of Revlimid above the competitive level results in substantial part from a significant imperfection in the United States marketplace for prescription pharmaceuticals. Branded drug manufacturers can exploit this imperfection in order to obtain or maintain market power.

251. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the product choice and the payment obligation, the product's price plays an appropriate role in the person's choice and, consequently, manufacturers have an appropriate incentive to reduce their prices to the competitive level.

252. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing

many pharmaceutical products, including Revlimid, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer) has the obligation to pay for it.

253. Brand manufacturers, including Celgene, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

254. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity, in turn, gives brand manufacturers the ability to raise the price of their brand drugs to levels substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as “market power.” The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Revlimid.

255. During the relevant time, Defendants had monopoly power in the market for Revlimid and its generic equivalents because they had the power to exclude competition and

raise or maintain the price of these drugs to supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

256. There are two other immunomodulatory agents on the market—Thalomid and Pomalyst²³—which are both owned by Celgene. Even so, the existence of these other immunomodulatory agents did not constrain the price of brand or generic Revlimid to the competitive level. Defendants needed to control only Revlimid and its AB-rated generic equivalents, and no other products, in order to maintain the price of brand and generic Revlimid at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Revlimid without a volume limitation could prevent Defendants from profitably maintaining prices at supracompetitive levels.

257. The brand and generic Revlimid sold by Defendants are therapeutically differentiated from the two other available immunomodulatory agents, Thalomid and Pomalyst. The exact mechanisms of action for each of the three immunomodulatory agents are unclear, but they are believed to work through different mechanisms in the body. Revlimid is a proprietary small molecule compound, taken orally, that treats multiple myeloma through multiple mechanisms of action, including immune activation, antiangiogenesis agents (which prevent new blood vessels from forming), and apoptosis properties (which promote cancer cell death). It was developed as an alternative to Thalomid and has been shown to have more effective bioavailability (due to increased stability) and stronger antiangiogenesis abilities than thalidomide. While Revlimid is approved for patients who have previously received one prior

²³ Neither Thalomid nor Polymast currently have an AB-rated generic on the market.

treatment, Pomalyst is only FDA-approved for those who have previously tried two prior treatments.

258. To the extent that Plaintiffs are required to prove market power through circumstantial evidence by first defining a relevant product market, Plaintiffs allege that the relevant antitrust market is the market for Revlimid and its AB-rated generic equivalents.

259. At all relevant times, the Defendants were protected by high barriers to entry due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or may assertedly be covered by patents or other forms of intellectual property. Defendants' unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants lacked the ability to enter the market and/or expand output quickly in the short run in response to Defendants' higher prices or reduced output.

260. The relevant geographic market is the United States and its territories. Defendant Celgene's market share in the relevant market was 100% until Natco's entry in 2022.

VIII. EFFECT ON INTERSTATE COMMERCE

261. During the relevant time period, Defendants manufactured, sold, and shipped Revlimid and generic Revlimid across state lines in an uninterrupted flow of interstate commerce.

262. During the relevant time period, Plaintiffs and Class members purchased substantial amounts of Revlimid and/or generic Revlimid directly from Defendants. As a result

of Defendants' illegal conduct, Plaintiffs and Class members were compelled to pay, and did pay, artificially inflated prices for Revlimid and generic Revlimid.

263. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged herein, within the flow of, and substantially affecting, interstate commerce, including in this district.

IX. CLASS ACTION ALLEGATIONS

264. Plaintiffs bring this action on behalf of themselves and, under Federal Rules of Civil Procedure 23(a) and 23(b)(2) and (b)(3), as representatives of a Class defined (with further limitations set forth in the Claims for Relief below) as:

All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Revlimid or generic Revlimid, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period December 22, 2015 through and until the anticompetitive effects of Defendants' conduct cease (the "Class").

265. Excluded from the Classes are:

- a. Defendants and any of their officers, directors, management, employees, subsidiaries, and affiliates.
- b. Federal and state government entities, except for cities, towns, municipalities or
- c. counties with self-funded prescription drug plans;
- d. Fully insured health plans, i.e., plans for which the insurer bears 100% of the risk
- e. for the reimbursement obligations to members;
- f. Pharmacy Benefit Managers; and
- g. The Judges in this case and any members of their immediate families.

266. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The Class is readily identifiable from information and records in Defendants' possession.

267. Plaintiffs' claims are typical of those of the Class members. Plaintiffs and all Class members were damaged by the same wrongful conduct of the Defendants—i.e., as a result of Defendants' conduct, Class members paid artificially inflated prices for Revlimid and AB-rated generic equivalents.

268. Plaintiffs will fairly and adequately protect and represent the Class's interests. The Plaintiffs' interests are coincident with, and not antagonistic to, those of the other Class members.

269. Counsel who represent Plaintiffs are experienced in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

270. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

271. Questions of law and fact common to the Class include:

- a. Whether the Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;
- b. Whether there exist any legitimate procompetitive reasons for some or all of the Defendants' conduct;

- c. To the extent any such procompetitive benefits exist, whether there were less restrictive means of achieving them;
- d. Whether direct proof of the Defendants' monopoly power is available and, if so, whether it is sufficient to prove the Defendants' monopoly power without the need to define the relevant market;
- e. Whether the Defendants' scheme, in whole or in part, has substantially affected interstate commerce;
- f. Whether the Defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the Plaintiffs and the Class members;
- g. Whether Defendants conspired to delay generic competition for Revlimid;
- h. Whether Celgene's payments to Natco to delay marketing its generic product were large and unjustified;
- i. Whether Celgene's payments to Apotex to delay marketing its generic product were large and unjustified;
- j. Whether Celgene's payments to Cipla to delay marketing its generic product were large and unjustified;
- k. Whether Celgene's payments to Dr. Reddy's to delay marketing its generic product were large and unjustified;
- l. Whether Celgene's payments to Lotus to delay marketing its generic product were large and unjustified;
- m. Whether Celgene's payments to Mylan to delay marketing its generic product were large and unjustified;
- n. Whether Celgene's payments to Zydus to delay marketing its generic product were large and unjustified;
- o. Whether the payments were necessary to yield some cognizable, non-pretextual procompetitive benefit;
- p. Whether Defendants' conduct harmed competition;
- q. Whether Defendants' unlawful conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Revlimid; and
- r. The quantum of overcharges paid by the Class in the aggregate.

272. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that they could not practicably pursue individually, substantially outweigh potential difficulties in management of this class action.

273. Defendants' anticompetitive conduct has imposed, and unless Plaintiffs obtain equitable relief will continue to impose, a common antitrust injury on Plaintiffs and all Class members. Defendants' anticompetitive conduct and their relationships with the Class members have been substantially uniform. Defendants have acted and refused to act on grounds that apply generally to the Class, and injunctive and other equitable relief is appropriate respecting the Class as a whole.

274. Plaintiffs know of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

X. PRIOR LITIGATION

275. End-payor plaintiffs previously brought suit against Celgene alleging antitrust violations for conduct related to Revlimid. *See* Am. Consol. Compl., *In re Thalomid and Revlimid Antitrust Litig.*, No. 2:14-cv-06997-KSH-CLW, ECF No. 143 (D.N.J. Aug. 1, 2017). The parties settled that litigation on March 30, 2020. *See* Settlement Agreement, *In re Thalomid and Revlimid Antitrust Litig.*, No. 2:14-cv-06997-KSH-CLW, ECF No. 312-3 (D.N.J. Aug. 1, 2017) ("Thalomid/Revlimid Settlement"). The release associated with that settlement does not, however, impact or preclude the claims raised in this Amended Class Action Complaint.

276. This suit is brought on behalf of end-payor purchasers who bought Revlimid in states not covered by the Thalomid/Revlimid Settlement. The settlement class was limited to “all persons or entities who purchased and/or paid for some or all of the purchase price of Thalomid or Revlimid in any form, before the Preliminary Approval Date^[24], in *California, the District of Columbia, Florida, Kansas, Maine, Massachusetts, Michigan, Nebraska, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, or Tennessee*, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries” Thalomid/Revlimid Settlement, ECF No. 312-3, at 4-5 (emphasis added). Here, Plaintiffs seek damages for purchases of Revlimid made in additional states, including Alaska, Connecticut, Hawaii, Illinois, Iowa, Kansas, Maryland, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Mexico, North Dakota, South Carolina, South Dakota, Utah, Vermont, West Virginia, and Wisconsin.

277. This Amended Class Action Complaint also asserts claims against a party not covered by the prior release. The only party released under to the Thalomid/Revlimid Settlement was brand manufacturer “Celgene, its predecessors, successors, subsidiaries, parents, Affiliates, divisions, and departments (including but not limited to the Bristol-Myers Squibb Company), and each of their respective officers, directors, employees, agents, attorneys, servants, and representatives, and the predecessors, successors, heirs, executors, administrators, and assigns of each of the foregoing.” ECF No. 312-3, at 4. This action asserts claims against Teva, which is not covered by the prior release.

²⁴ “Preliminary Approval Date” refers to August 1, 2019, the date on which the Court entered an order granting preliminary approval of the Settlement Agreement. *See* ECF No. 312 at 4, ECF No. 290 Order granting Motion for Preliminary Approval.

278. And this Amended Class Action Complaint asserts claims for conduct occurring after the “Effective Date” of the Thalomid/Revlimid Settlement. The “Effective Date” as defined under that agreement is November 19, 2020, the date on which the deadline to appeal the Court’s entry of final judgment expired. *See* ECF No. 312-3, at 3; *see also* Fed. R. App. P. 4(a)(1)A). This Amended Class Action Complaint alleges anticompetitive conduct by Celgene arising from its settlements with generic manufacturers occurring after the Effective Date. This includes Celgene’s unlawful payments to Cipla on December 11, 2020, to Apotex on March 10, 2021, to Zydus on March 24, 2021, and to Mylan on July 23, 2021.

XI. CLAIMS FOR RELIEF

COUNT ONE VIOLATION OF 15 U.S.C. § 1 (AGAINST CELGENE AND TEVA)

279. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

280. Plaintiffs bring this claim on behalf of a nationwide class.

281. Defendants violated 15 U.S.C. § 1 by entering into and adhering to an unreasonable restraint of trade, defined as Celgene’s reverse payments to Natco, in exchange for Natco’s delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

282. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

283. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

284. As a direct result of these Defendants' violation of 15 U.S.C. § 1, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Defendants' conduct unlawful.

COUNT TWO
VIOLATION OF 15 U.S.C. § 1
(AGAINST CELGENE WITH RESPECT TO LOTUS AND ALVOGEN)

285. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

286. Plaintiffs bring this claim on behalf of a nationwide class.

287. Celgene, Lotus, and Alvogen violated 15 U.S.C. § 1 by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Lotus and Alvogen, in exchange for their delaying unrestrained sale of their generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

288. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

289. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

290. As a direct result of Celgene's violation of 15 U.S.C. § 1, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

COUNT THREE
VIOLATION OF 15 U.S.C. § 1
(AGAINST CELGENE WITH RESPECT TO DR. REDDY'S)

291. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

292. Plaintiffs bring this claim on behalf of a nationwide class.

293. Celgene and Dr. Reddy's violated 15 U.S.C. § 1 by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Dr. Reddy's, in exchange for Dr. Reddy's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

294. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

295. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

296. As a direct result of Celgene's violation of 15 U.S.C. § 1, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

COUNT FOUR
VIOLATION OF 15 U.S.C. § 1
(AGAINST CELGENE WITH RESPECT TO CIPLA)

297. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

298. Plaintiffs bring this claim on behalf of a nationwide class.

299. Celgene and Cipla violated 15 U.S.C. § 1 by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Cipla, in exchange for Cipla's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

300. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

301. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

302. As a direct result of Celgene's violation of 15 U.S.C. § 1, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

COUNT FIVE
VIOLATION OF 15 U.S.C. § 1
(AGAINST CELGENE WITH RESPECT TO APOTEX)

303. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

304. Plaintiffs bring this claim on behalf of a nationwide class.

305. Celgene and Apotex violated 15 U.S.C. § 1 by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Apotex, in exchange for Apotex's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

306. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

307. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

308. As a direct result of Celgene's violation of 15 U.S.C. § 1, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

COUNT SIX
VIOLATION OF 15 U.S.C. § 1
(AGAINST CELGENE WITH RESPECT TO ZYDUS AND CADILA)

309. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

310. Plaintiffs bring this claim on behalf of a nationwide class.

311. Celgene, Zydus, and Cadila violated 15 U.S.C. § 1 by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Zydus and Cadila, in exchange for their delaying unrestrained sale of their generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

312. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

313. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

314. As a direct result of Celgene's violation of 15 U.S.C. § 1, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

COUNT SEVEN
VIOLATION OF 15 U.S.C. § 1
(AGAINST CELGENE WITH RESPECT TO MYLAN)

315. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

316. Plaintiffs bring this claim on behalf of a nationwide class.

317. Celgene and Mylan violated 15 U.S.C. § 1 by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Mylan, in exchange for Mylan's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

318. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

319. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

320. As a direct result of Celgene's violation of 15 U.S.C. § 1, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

COUNT EIGHT
VIOLATION OF 15 U.S.C. § 1
(AGAINST ALL DEFENDANTS)

321. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

322. Plaintiffs bring this claim on behalf of a nationwide class.

323. Defendants violated 15 U.S.C. § 1 by entering into and adhering to an unreasonable restraint of trade, defined as their agreement to allocate among themselves the market for branded and generic Revlimid.

324. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

325. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the restraint was not necessary to achieve such a purpose, and, in any event, such procompetitive

effects would be outweighed by the restraint's anticompetitive effects on purchasers, competition, and consumers.

326. As a direct result of these Defendants' violation of 15 U.S.C. § 1, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Defendants' conduct unlawful.

COUNT NINE
VIOLATION OF 15 U.S.C. § 2
(AGAINST CELGENE)

327. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

328. Plaintiffs bring this claim on behalf of a nationwide class.

329. Celgene violated 15 U.S.C. § 2 by monopolizing and conspiring to monopolize the market for Revlimid and its AB-rated generic equivalents in the United States.

330. At all relevant times, Celgene possessed substantial market power (i.e., monopoly power) with respect to Revlimid and its AB-rated generic equivalents. Celgene possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

331. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

332. As alleged extensively above, Celgene willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than greater business acumen, and injured Plaintiffs and the Class thereby.

333. Celgene's conscious objective was to further its dominance through exclusionary conduct.

334. As stated more fully above, Celgene knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by:

- Making a series of reverse payments in exchange for delayed generic entry; and
- Allocating the market for Revlimid and its generic equivalents.

335. Celgene's reverse payments and market allocation constituted exclusionary conduct the purpose and effect of which is to willfully maintain monopoly power, which harms purchasers, the competitive process, and consumers, in violation of Section 2 of the Sherman Act.

336. To the extent that Celgene is permitted to assert one, there is and was no cognizable, non-pretextual, procompetitive justification for its exclusionary conduct that outweighs the harmful effects. Even if there were some conceivable justification that Celgene were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

337. Plaintiffs and the Class have been injured, and unless they obtain equitable relief will continue to be injured, in their business and property as a result of Celgene's continuing monopolization in violation of Section 2 of the Sherman Act.

COUNT TEN
VIOLATION OF 15 U.S.C. § 2
(AGAINST ALL DEFENDANTS)

338. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

339. Plaintiffs bring this claim on behalf of a nationwide class.

340. Each Defendant violated 15 U.S.C. § 2 by monopolizing and conspiring to monopolize the market for Revlimid and its AB-rated generic equivalents in the United States.

341. At all relevant times, Celgene possessed substantial market power (i.e., monopoly power) with respect to Revlimid and its AB-rated generic equivalents. Celgene possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

342. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

343. As alleged extensively above, each Defendant willfully maintained and conspired to maintain monopoly power by using restrictive or exclusionary conduct, rather than greater business acumen, and injured Plaintiffs and the Class thereby.

344. Each Defendant's conscious objective was to create and maintain the monopoly through exclusionary conduct.

345. As stated more fully above, each Defendant knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by:

- Entering into a reverse-payment agreement that traded a reverse payment in exchange for delayed generic entry; and
- Allocating the market for Revlimid and its generic equivalents.

346. The reverse payments and market allocation constituted exclusionary conduct the purpose and effect of which is to willfully maintain monopoly power, which harms purchasers, the competitive process, and consumers, in violation of Section 2 of the Sherman Act.

347. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual, procompetitive justification for the exclusionary conduct that outweighs the harmful effects. Even if there were some conceivable justification that Defendants were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

348. Plaintiffs and the Class have been injured, and unless they obtain equitable relief will continue to be injured, in their business and property as a result of each Defendant's continuing monopolization in violation of Section 2 of the Sherman Act.

COUNT ELEVEN
CONTRACT AND CONSPIRACY
IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST CELGENE AND TEVA WITH RESPECT TO NATCO)

349. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

350. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below, excluding, as to Celgene, purchases as to which the claims were released by the Thalomid/Revlimid Settlement.

351. Celgene, Natco, and Teva violated state antitrust and other statutes, as set forth below, by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Natco, in exchange for Natco's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

352. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

353. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

354. As a direct result of Celgene's and Teva's violations of these state statutes, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the state laws were designed to prevent, and flows from that which makes Defendants' conduct unlawful.

355. By engaging the foregoing conduct, Celgene and Teva intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.

- e. Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- g. Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.
- j. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- q. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.

- t. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- y. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.
- aa. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- bb. Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT TWELVE
CONTRACT AND CONSPIRACY
IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST CELGENE WITH RESPECT TO LOTUS AND ALVOGEN)

356. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

357. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below, excluding purchases as to which the claims were released by the Thalomid/Revlimid Settlement.

358. Celgene, Lotus, and Alvogen violated state antitrust and other statutes, as set forth below, by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Lotus and Alvogen, in exchange for their delaying unrestrained sale of their generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

359. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

360. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

361. As a direct result of Celgene's violation of these state statutes, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the state laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

362. By engaging the foregoing conduct, Celgene intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.

- b. Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.
- e. Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- g. Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.
- j. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.

- q. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- y. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.
- aa. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- bb. Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT THIRTEEN
CONTRACT AND CONSPIRACY
IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST CELGENE WITH RESPECT TO DR. REDDY'S)

363. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

364. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below, excluding purchases as to which the claims were released by the Thalomid/Revlimid Settlement.

365. Celgene and Dr. Reddy's violated state antitrust and other statutes, as set forth below, by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Dr. Reddy's, in exchange for Dr. Reddy's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

366. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

367. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

368. As a direct result of Celgene's violation of these state statutes, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the state laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

369. By engaging the foregoing conduct, Celgene intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.
- e. Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- g. Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.
- j. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.

- n. Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- q. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- y. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.
- aa. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- bb. Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT FOURTEEN
CONTRACT AND CONSPIRACY
IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST CELGENE WITH RESPECT TO CIPLA)

370. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

371. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below.

372. Celgene and Cipla violated state antitrust and other statutes, as set forth below, by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Cipla, in exchange for Cipla's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

373. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

374. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

375. As a direct result of these Celgene's violation of these state statutes, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is

of the type the state laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

376. By engaging the foregoing conduct, Celgene intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.
- e. Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- g. Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.
- j. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.

- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- q. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- y. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.
- aa. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.

bb. Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT FIFTEEN
CONTRACT AND CONSPIRACY
IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST CELGENE WITH RESPECT TO APOTEX)

377. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

378. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below.

379. Celgene and Apotex violated state antitrust and other statutes, as set forth below, by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Apotex, in exchange for Apotex's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

380. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

381. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

382. As a direct result of Celgene's violation of these state statutes, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having

paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called “overcharges,” is of the type the state laws were designed to prevent, and flows from that which makes Celgene’s conduct unlawful.

383. By engaging the foregoing conduct, Celgene intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members’ purchases in Arizona and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members’ purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members’ purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4501, et seq., with respect to Class members’ purchases in the District of Columbia and/or purchases by D.C. residents.
- e. Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members’ purchases in Hawaii and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members’ purchases in Illinois and/or purchases by Illinois residents.
- g. Iowa Code § 553.1, et seq., with respect to Class members’ purchases in Iowa and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members’ purchases in Kansas and/or purchases by Kansas residents.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members’ purchases in Maine and/or purchases by Maine residents.
- j. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members’ purchases in Maryland and/or purchases by Maryland residents.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members’ purchases in Michigan and/or purchases by Michigan residents.

- l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- q. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- y. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.

- z. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.
- aa. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- bb. Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT SIXTEEN
CONTRACT AND CONSPIRACY
IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST CELGENE WITH RESPECT TO ZYDUS AND CADILA)

384. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

385. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below.

386. Celgene, Zydus, and Cadila violated state antitrust and other statutes, as set forth below, by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Zydus and Cadila, in exchange for their delaying unrestrained sale of their generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

387. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

388. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

389. As a direct result of Celgene's violation of these state statutes, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the state laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

390. By engaging the foregoing conduct, Celgene intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.
- e. Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- g. Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.

- j. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- q. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.

- x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- y. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.
- aa. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- bb. Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT SEVENTEEN
CONTRACT AND CONSPIRACY
IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST CELGENE WITH RESPECT TO MYLAN)

391. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

392. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below.

393. Celgene and Mylan violated state antitrust and other statutes, as set forth below, by entering into and adhering to an unreasonable restraint of trade, defined as Celgene's reverse payments to Mylan, in exchange for Mylan's delaying unrestrained sale of its generic Revlimid until February 1, 2026, and allocating the market for branded and generic Revlimid.

394. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

395. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraints. Even if there were some conceivable and cognizable justification, the restraints were not necessary to achieve such a purpose, and, in any event, such

procompetitive effects would be outweighed by the restraints' anticompetitive effects on purchasers, competition, and consumers.

396. As a direct result of Celgene's violation of these state statutes, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the state laws were designed to prevent, and flows from that which makes Celgene's conduct unlawful.

397. By engaging the foregoing conduct, Celgene intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.
- e. Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- g. Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.

- h. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.
- j. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- q. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.

- w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- y. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.
- aa. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- bb. Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT EIGHTEEN
CONTRACT AND CONSPIRACY
IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST ALL DEFENDANTS)

398. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

399. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below, excluding, as to Celgene, purchases as to which the claims were released by the Thalomid/Revlimid Settlement.

400. Each Defendant violated state antitrust and other statutes, as set forth below, by entering into and adhering to an unreasonable restraint of trade, defined as their agreement to allocate among themselves and the other generic manufacturers the market for branded and generic Revlimid.

401. At all relevant times, Celgene had substantial market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

402. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the restraint was not necessary to achieve such a purpose, and, in any event, such procompetitive effects would be outweighed by the restraint's anticompetitive effects on purchasers, competition, and consumers.

403. As a direct result of these Defendants' restraint of trade in violation of state law, Plaintiffs and other Class members have been injured, and unless Plaintiffs obtain equitable relief will continue to be injured, in their business or property. Plaintiffs' and Class members' injury consists of having paid higher prices for their Revlimid requirements, and continuing to pay higher prices, than they would have paid in the absence of the violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, and flows from that which makes Defendants' conduct unlawful.

404. By engaging the foregoing conduct, each Defendant intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.
- e. Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.

- f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- g. Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.
- j. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- q. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.

- u. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- y. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.
- aa. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- bb. Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT NINETEEN
MONOPOLIZATION UNDER STATE LAW
(AGAINST CELGENE)

405. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

406. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below, excluding purchases as to which the claims were released by the Thalomid/Revlimid Settlement.

407. Celgene violated the state laws listed below by monopolizing and conspiring to monopolize the market for Revlimid and its AB-rated generic equivalents in the United States.

408. At all relevant times, Celgene possessed substantial market power (i.e., monopoly power) with respect to Revlimid and its AB-rated generic equivalents. Celgene possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

409. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

410. As alleged extensively above, Celgene willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than greater business acumen, and injured Plaintiffs and the Class thereby.

411. Celgene's conscious objective was to further its dominance through exclusionary conduct.

412. As stated more fully above, Celgene knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by:

- Making a series of reverse payments in exchange for delayed generic entry; and
- Allocating the market for Revlimid and its generic equivalents.

413. Celgene's reverse payments and market allocation constituted exclusionary conduct the purpose and effect of which is to willfully maintain monopoly power, which harms purchasers, the competitive process, and consumers, in violation of Section 2 of the Sherman Act.

414. To the extent that Celgene is permitted to assert one, there is and was no cognizable, non-pretextual, procompetitive justification for its exclusionary conduct that outweighs the harmful effects. Even if there were some conceivable justification that Celgene

were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

415. Plaintiffs and the Class have been injured, and unless they obtain equitable relief will continue to be injured, in their business and property as a result of Celgene's continuing monopolization.

416. By engaging in the foregoing conduct, Celgene intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1403, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16700, with respect to Class members' purchases in California and/or purchases by California residents.
- c. C.G.S.A. §§ 35-27, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4503, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by District Columbia residents.
- e. Fla. Stat. §§ 501.201, et seq., with respect to Class members' purchases in Florida and/or purchases by Florida residents, and such conduct constitutes a predicate act under the Florida Deceptive Practices Act.
- f. Haw. Rev. Stat. §§ 480-2, 480-9, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.
- g. 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- h. Iowa Code § 553.5, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.
- i. Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.
- j. Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.

- k. MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.
- l. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- m. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or purchases by Minnesota residents.
- n. Miss. Code Ann. §§ 75-21-3, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.
- o. Mo. Rev. Stat. §§ 407.020, et seq., with respect to Class members' purchase in Missouri and/or purchases by Missouri residents.
- p. Mont. Code Ann. §§ 30-14-101, et seq., with respect to Class members' purchases in Montana and/or purchases by Montana residents.
- q. Neb. Rev. Stat. Ann. §§ 59-802, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- r. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- s. N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- t. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- u. N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.
- v. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- w. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.
- x. Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.
- y. P.R. Laws Ann. tit. 10, §§ 260, *et seq.*, with respect to Class members' purchases in Puerto Rico and/or purchases by Puerto Rico residents.

- z. R.I. Gen. Laws §§ 6-36-5 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.
- aa. S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.
- bb. Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.
- cc. Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by Arizona residents.
- dd. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to Class members' purchases in Vermont and/or purchases by Vermont residents.
- ee. W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- ff. Wis. Stat. §§ 133.03, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

COUNT TWENTY
VIOLATION OF STATE
CONSUMER PROTECTION LAWS
(AGAINST ALL DEFENDANTS)

417. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

418. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below, excluding, as to Celgene, purchases as to which the claims were released by the Thalomid/Revlimid Settlement.

419. Defendants engaged in unfair methods of competition or unfair and/or unconscionable conduct in violation of the state consumer protection statutes listed below.

420. There was and is a gross disparity between the price that Plaintiffs and the Class members paid for Revlimid and the value they received. Much more affordable generic Revlimid

would have been and would be available, and prices for Revlimid would have been and would be far lower, but for Defendants' unfair competition or unfair and/or unconscionable conduct.

421. Celgene implemented shockingly large price increases, resulting in an over 400% increase in price for Revlimid since 2005.

422. Lower-priced generic Revlimid would have been and would be available, and prices for Revlimid would have been and would be far lower, but for Defendants' unfair competition or unfair and/or unconscionable conduct.

423. As a direct and proximate result of Defendants' unfair competition or unfair and/or unconscionable conduct, Plaintiffs and Class members were: (i) denied the opportunity to purchase lower-priced generic Revlimid; and (ii) forced to pay higher prices for Revlimid than they would have paid but for Defendants' unlawful conduct.

424. The gravity of harm from Defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiffs and Class members could not reasonably have avoided injury from Defendants' wrongful conduct.

425. By engaging in such conduct, Defendants violated the following consumer protection laws:

- a. Alaska Stat. Ann. §§ 45.50.471, et seq., with respect to Class members' purchases in Alaska and/or purchases by Alaska residents.
- b. Ariz. Rev. Stat. Ann. §§ 44-1521, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.
- c. Ark. Code Ann. §§ 4-88-101, et seq., with respect to Class members' purchases in Arkansas and/or purchases by Arkansas residents.
- d. Cal. Bus. & Prof Code §§ 17200, et seq., with respect to Class members' purchases in California and/or purchases by California residents. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to class members. There are no countervailing benefits to class members and any utility of Defendants' conduct is outweighed by the consequences to

class members. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above and violates Cal. Health & Safety Code § 134002.

- e. D.C. Code §§ 28-3901, et seq., with respect to Class members' purchases in D.C. and/or purchases by D.C. residents.
- f. Fla. Stat. §§ 501.201, et seq., with respect to Class members' purchases of in Florida and/or purchases by Florida residents.
- g. Haw. Rev. Stat. §§ 481-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.
- h. 815 Ill. Comp. Stat. 505/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.
- i. Mass. Gen. Laws ch. 93A, §§ 1 et seq., with respect to Class members' purchases in Massachusetts and/or purchases by Massachusetts residents.
- j. Mich. Comp. Laws §§ 445.901, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.
- k. Mo. Rev. Stat. §§ 407.010, et seq., with respect to Class members' purchases in Missouri and/or purchases by Missouri residents.
- l. Mont. Code §§ 30-14-101, et seq., with respect to Class members' purchases in Montana and/or purchases by Montana residents.
- m. Neb. Rev. Stat. §§ 59-1601, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.
- n. Nev. Rev. Stat. Ann. §§ 598.0903, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.
- o. N.H. Rev. Stat. Ann. §§ 358-A:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.
- p. N.M. Stat. Ann. §§ 57-12-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.
- q. N.C. Gen. Stat. §§ 75-1.1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.
- r. R.I. Gen. Laws §§ 6-13.1-1, et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents, for personal, family and/or household use.

- s. S.C. Code Ann. §§ 39-5-20, et seq., with respect to Class members' purchases in South Carolina and/or purchases by South Carolina residents. Defendants engaged in unfair methods of competition and/or unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.
- t. Utah Code Ann. §§ 13-11-1, et seq., with respect to Class members' purchases in Utah and/or purchases by Utah residents for personal, family, or household purposes.
- u. Vt. Stat Ann. tit. 9, § 2453, et seq., with respect to Class members' purchases in Vermont and/or purchases by Vermont residents. Defendants engaged in unfair methods of competition, unfair practices, and/or deceptive practices in the conduct of trade and commerce.
- v. W. Va. Code §§ 46A-6-101, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.
- w. Wis. Stat. § 100.20, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

426. Plaintiffs and Class members have been injured in their business and property by reason of Defendants' unfair competition or unfair and/or unconscionable conduct. Their injury consists of paying higher prices for Revlimid than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT TWENTY-ONE
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

427. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

428. Plaintiffs bring this claim on behalf of a class of purchasers in the states whose law is invoked below, excluding, as to Celgene, purchases as to which the claims were released by the Thalomid/Revlimid Settlement.

429. Plaintiffs bring this Court on behalf of the Nationwide Class except for Delaware, Georgia, Indiana, Kentucky, Louisiana, New Jersey, Ohio, Oklahoma, Pennsylvania, Texas, Virginia, Washington, and Wyoming.

430. To the extent required, this claim is pleaded in the alternative to the other claims in this Amended Class Action Complaint.

431. Defendants have reaped and retained substantially higher profits due to their unlawful scheme.

432. Plaintiffs and Class members have conferred and continue to confer an economic benefit upon Defendants in the form of profits resulting from the unlawful overcharges from Revlimid sales described herein, to the economic detriment of Plaintiffs and Class members.

433. Defendants' financial gain from their unlawful conduct is traceable to overpayments for Revlimid by Plaintiffs and Class members.

434. It would be futile for Plaintiffs and Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Revlimid, as those intermediaries are not liable and would not compensate Plaintiffs and Class members for Defendants' unlawful conduct.

435. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiffs and Class members for Revlimid sold by Celgene during the Class Period.

436. The financial benefits the Defendants derived from overcharging Plaintiffs and Class members for Revlimid is a direct and proximate result of Defendants' unlawful practices described herein.

437. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiffs and Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

438. It would be wrong and inequitable, under unjust enrichment principles under the laws of the relevant jurisdictions for Defendants to be permitted to retain any of the overcharges that Plaintiffs and Class members paid for Revlimid that were derived from Defendants' unlawful practices described herein.

439. Defendants are aware of and appreciate the benefits that Plaintiffs and Class members have bestowed upon them.

440. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of the Plaintiffs and Class members.

441. Plaintiffs and Class members are entitled to the amount of Defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct, and to the establishment of a constructive trust consisting of such amount, from which Plaintiffs and Class members may make claims on a pro rata basis.

XII. DEMAND FOR JUDGMENT

442. WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, respectfully demand that this Court:

- a. Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and declare Plaintiffs as the representatives of the Class;
- b. Enter joint and several judgments against Defendants and in favor of Plaintiffs and the Class;
- c. Award the Class damages (i.e., three times overcharges) in an amount to be determined at trial;

- d. Grant permanent injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to remedy the ongoing anticompetitive effects of Defendants' unlawful conduct;
- e. Enter a declaratory judgment a declaratory judgment, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), that Defendants' conduct constitutes a violation of Sections 1 and 2 of the Sherman Act and other applicable law;
- f. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and
- g. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

443. Pursuant to Fed. Civ. P. 38, Plaintiffs on behalf of themselves and the proposed Class demand a trial by jury on all issues so triable.

Dated: February 16, 2023

By: /s/ Natalie Finkelman Bennett

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CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2023, the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

Parties may access this filing through the Court's system.

/s/Natalie Finkelman Bennett